

# FSMA TAN POPULAR TOPICS

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# LABORATORY ACCREDITATION FOR ANALYSES OF FOODS (LAAF)

## LAAF 1. What testing is covered under the LAAF final rule?

After the LAAF final rule is fully implemented, owners and consignees will be required to use a LAAF-accredited laboratory for food testing:

- to support removal from an [import alert](#) through successful consecutive testing (e.g., to get a food product or firm removed from [the red list](#));
- to support admission of an imported food (e.g., articles of human or animal food, and U.S. goods returned that are articles of food) detained at the border because it is or appears to be in violation of the Federal Food, Drug, and Cosmetic Act (e.g., products that contain or appear to contain unapproved food additives, including unauthorized food contact substances);
- required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests related to shell eggs, sprouts, and bottled drinking water);
- required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow FDA to require use of a LAAF-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances; and
- conducted in connection with certain administrative processes (e.g., testing submitted in connection with an appeal of an administrative detention order).

## LAAF 2. What is a Directed Food Laboratory Order?

A directed food laboratory order is a precise new tool that allows FDA to require that food testing be conducted under the LAAF rule in certain circumstances. See [21 CFR 1.1107\(a\)\(2\); 1.1108](#). The legal standard for issuing a directed food laboratory order is, “as required by the [FDA], as the [FDA] deems appropriate, to address an identified or suspected food safety problem” (FD&C Act section 422(b)(1)(A)(ii)). Notably, there are two prongs to the standard, both of which must be satisfied for FDA to consider use of a directed food laboratory order. First, FDA interprets “as the [FDA] deems appropriate,” to mean that a directed food laboratory order would generally only be appropriate if FDA has reason to question a firm’s past or present test results. Second, an “identified or suspected food safety problem” must also exist.

An “identified food safety problem” could be present when a specific article of food violates a food safety provision of the FD&C Act or implementing regulations (e.g., when an article of food is adulterated). A “suspected food safety problem” would not be satisfied by the common or usual characteristics of a food or the manner in which the food is typically produced. Rather, a “suspected food safety problem” typically would have a basis in fact about a particular article of food (e.g., a lot or batch) or food production environment (e.g., a specific facility). A variety of circumstances may generate suspicion of a food safety problem. FDA will consider all applicable regulations and relevant circumstances in determining whether an identified or suspected food safety problem exists.

One example of a situation in which a directed food laboratory order may be useful and appropriate is where FDA is investigating an outbreak of illnesses related to a firm, and FDA subsequently learns the firm has a history of falsifying food testing records.

We note that the purpose of routine product and environmental testing under the preventive controls for human food and food for animal regulations is to verify that preventive controls are consistently implemented and are effective ([21 CFR 117.165\(a\)](#) and [507.49\(a\)](#)). Accordingly, such routine testing does not address an identified or suspected food safety problem and would not by itself be a sufficient basis for a directed food laboratory order.

A directed food laboratory order will specify the food product or environment to be tested and one or more validated test methods ([21 CFR 1.1108\(b\)](#)). Only certain FDA officials have the authority to issue a directed food laboratory order (e.g., the Associate and Deputy Associate Commissioners for Regulatory Affairs); see [Staff Manual Guide 1410.310](#).

### **LAAF 3. Do LAAF-accredited laboratories that conduct testing outside of the LAAF program need to send those test results to FDA?**

No. LAAF-accredited laboratories need to send test results to FDA only when the testing is conducted under the LAAF rule. If an owner or consignee hires a LAAF-accredited laboratory to conduct testing outside the scope of the LAAF rule, the laboratory does not need to submit such test results to FDA. See [21 CFR 1.1152\(b\)\(1\)](#).

## **PREVENTIVE CONTROLS FOR HUMAN AND ANIMAL FOOD REQUIREMENTS**

### **PC.1 What are the major requirements under the final preventive controls rules?**

They can be found in two fact sheets:

- [Preventive Controls for Human Food At-A-Glance Fact Sheet](#)
- [Preventive Controls for Animal Food At-A-Glance Fact Sheet](#)

## ***ENVIRONMENTAL TESTING & MONITORING***

**PC.2 Product testing and environmental monitoring are in the final rules. When would companies need to apply these activities?**

The preventive controls final rules require that a facility verify that hazards are being controlled and take corrective action to prevent contamination; and product testing and environmental monitoring are examples of steps a firm may take. A facility's decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, the FDA expects that facilities that produce foods that have frequently been associated with outbreaks of foodborne illness or pathogen contamination, or produce ready-to-eat foods for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such foods.

Similarly, a facility that identifies an environmental pathogen as a hazard requiring a preventive control, for example, sanitation controls, would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system.

## ***FOOD SAFETY PLAN***

**PC.3 The rule requires food facilities to have a written food safety plan that includes a hazard analysis and preventive controls. How often must that plan be reanalyzed?**

At least once every three years. The facility must also review portions of the food safety plan under certain circumstances, such as when a preventive control is found to be ineffective.

**PC.4 My company has three separate food facilities. Are we required to have three distinct facility-specific food safety plans even though we produce the exact same food product at all three facilities?**

The overall framework is directed to a facility. Thus, the preventive controls for human food rule establishes a requirement for every facility to have its own written food safety

plan. Even if a corporation makes or holds similar products at separate facilities, it is unlikely that the separate facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility including processing lines, technologies, and raw materials utilized as they will affect the approach to applying preventive controls such as allergen controls.

## ***PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI)***

### **PC.5 What is a preventive controls qualified individual?**

This is a new term in the final rule. A preventive controls qualified individual is someone who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. The written food safety plan required of food facilities must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. And the preventive controls qualified individual is charged with overseeing the validation that preventive controls are capable of controlling identified hazards and the records review.

### **PC.6 Do I need to employ a preventive controls qualified individual (PCQI)?**

The preventive controls for human food rule creates new requirements for covered domestic and foreign facilities producing human food to develop and implement a food safety plan based on hazard analysis and risk-based preventive controls. In general, the rule applies to facilities that have to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). However, there are a number of exemptions and modified requirements that may apply (see [21 CFR 117.5](#) for exemptions that may apply to your facility).

If no exemptions apply to you, then you are required to have a PCQI develop and implement your facility's food safety plan. A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

### **PC.7 How does a PCQI demonstrate that he or she is qualified to serve as a PCQI?**

The [preventive controls for human food final rule](#) specifies that a PCQI is a qualified individual who has successfully completed training in the development and application

of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

However, the rule does not require any specific certifications, including certification by the Food Safety Preventive Controls Alliance (FSPCA). An individual may voluntarily choose to attend the PCQI training provided through the FSPCA, but this is not mandatory. In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

**PC.8 I have many food safety certifications (HACCP, GFSI, SQF, BRC, etc). Do I still need to take the PCQI training from the FSPCA?**

The [preventive controls for human food rule](#) specifies that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

There are some differences in the requirements of the CGMP & PC rule compared to the requirements of HACCP regulations and other preventive-based food safety programs such that the training provided by the International HACCP Alliance/GFSI/SQF/BRC etc or other institutions might not be equivalent. Such an individual may need additional training specific to the CGMP & PC rule. However, the CGMP & PC rule does not require any specific certifications, including certification by the FSPCA. In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

**PC.9 I have worked as a food safety manager for a very long time. Do I need to take PCQI training, or does my job experience satisfy the requirements to be a PCQI?**

The [preventive controls for human food final rule](#) specifies that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

#### **PC.10 Can I use one PCQI for all my facilities, or must I have one PCQI for each facility?**

The [preventive controls for human food final rule](#) does not prohibit a company from utilizing the services of a single PCQI for multiple locations. Additionally, there are no restrictions on the proximity of the locations that are under the direction of any PCQI. Note, however, that each facility must have a PCQI prepare or oversee the preparation of a food safety plan specific to that facility in accordance with [21 CFR 117.126\(a\)\(2\)](#).

### ***QUALIFIED FACILITY DEFINITION***

#### **PC.11 What is a qualified facility?**

A "qualified facility" is (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) either:

- A "very small business," a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee), or
- A facility to which both of the following conditions apply: During the 3-year period preceding the applicable calendar year,
  - (1) the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
  - (2) the average annual monetary value of all food sold during the 3-year period

preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(See [21 CFR section 117.3](#) for definitions of "qualified facility," "very small business," and "qualified end-user")

#### **PC.12 What are the requirements applicable to a qualified facility?**

A qualified facility is exempt from subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of the preventive controls for human food rule. However, a qualified facility is subject to modified requirements. It must submit two attestations to FDA: (1) an attestation that it is a qualified facility and (2) either an attestation that it has identified potential hazards, is implementing preventive controls to address the hazards, and is monitoring performance of the preventive controls or an attestation that the facility is in compliance with non-federal food safety laws and regulations. Further, a consumer notification requirement may be applicable, depending on which attestation a qualified facility provides.

The compliance date for a business meeting the definition of a "qualified facility" (including a "very small business") is September 17, 2018. However, there is an earlier compliance date of January 1, 2016 for a facility to maintain (but not submit) financial records to support its status as a qualified facility.

The rule also establishes two additional compliance dates applicable to qualified facilities. First, it establishes December 17, 2018 as the compliance date for (1) the initial submission of the attestation by a facility that it is a qualified facility and (2) the attestation by a qualified facility about its food safety practices or that it is in compliance with non-federal food safety law. Second, it establishes January 1, 2020, as the compliance date for the consumer notification requirement. The consumer notification requirement applies to a qualified facility that submits an attestation that it is in compliance with applicable non-federal food safety law and requires such a facility to notify consumers as to the name and complete business address of the facility where the food was manufactured or processed.

#### **PC.13 What records must be kept by a qualified facility regarding its attestations?**

A qualified facility must maintain those records relied on to support the attestations (see [21 CFR section 117.201\(f\)](#)).

#### **PC.14 What form is used for qualified facility attestations?**

Form FDA 3942a (for Human Food) is an attestation form for a food facility meeting the definition of a “Qualified facility.” A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year. The attestations required must be:

- Submitted to FDA initially:
  - By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;
  - Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or
  - By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination; and
- Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.
- When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.

More information about the qualified facility attestation form can be found at:  
<https://www.fda.gov/food/registration-food-facilities/qualified-facility-attestation>

**PC.15 In determining whether my business meets the definition of a “very small business,” what is the meant by the “applicable calendar year”?**

The applicable calendar year is the year after the three calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the three calendar years used to determine whether a facility is a very small business are 2021-2023. The exception is when three calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations, the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

**PC.16 Does the final rule include provisions to appeal the withdrawal of a qualified facility exemption?**

Yes. The final rule provides procedures for a facility to appeal the withdrawal order and request an informal hearing. And there is a procedure for reinstating an exemption that was withdrawn.

## ***WHAT ARE THE DIFFERENCES BETWEEN THE NEW PC RULES AND HACCP?***

### **PC. 17 How are the preventive controls rules different from the Hazard Analysis and Critical Control Points (HACCP) system?**

The Hazard Analysis and Critical Control Points systems that many FDA-regulated manufacturers have in place are the foundation of the preventive controls regulations. Although there are similarities between the FSMA preventive controls requirements and the HACCP system, not every provision is identical. For example, in HACCP systems, controls are applied at critical control points (CCPs), whereas preventive controls include controls at CCPs or controls other than those at CCPs that are appropriate for food safety.

## ***MANUFACTURING AND PROCESSING ACTIVITIES***

### **PC.18 What are the manufacturing/processing activities allowed under the farm definition?**

Drying/dehydrating raw agricultural commodities that creates a distinct commodity, such as producing raisins and prunes from grapes and plums, and packaging and labeling such commodities, without additional manufacturing/processing are allowed under the farm definition. Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing, are other examples of manufacturing/processing activities that can be conducted under the farm definition.

## ***HUMAN FOOD BY-PRODUCTS USED FOR ANIMAL FOOD***

### **PC.19 What does this final rule specifically require human food facilities to do when providing a by-product for use as animal food?**

Processors already implementing human food safety requirements, such as brewers, would not need to implement additional preventive controls or Current Good Manufacturing Practice (CGMP) regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except to prevent physical and chemical contamination when holding and distributing the by-product. This regulation applies to human food facilities that both donate or sell a by-product for use in animal food. Labeling that identifies the by-product by the common or usual name

must be affixed to or accompany human food by-products for use as animal food when distributed.

Further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with CGMPs to ensure the animal food's safety and to make sure that the processing does not introduce hazards to the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product. In addition, unless they are a qualified facility or otherwise exempt from subpart C (hazard analysis and preventive controls) the facility would need to assess its processing and determine whether there are any hazards that would require a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control would document such a determination in its hazard analysis but would not need to establish preventive controls.

**PC.20 Do the preventive controls requirements apply to human food by-products for use in animal food that are dried, frozen or slightly modified specifically to facilitate storage and transportation?**

As written, the CGMP and hazard analysis and risk-based preventive control requirements of the Preventive Controls for Animal Food rule apply to manufacturing/processing activities, including those performed to facilitate storage and transportation, unless an exemption applies. In draft guidance #239 Human Food By-Products for Use as Animal Food, we identified several manufacturing/processing activities for which there would only be limited CGMP requirements related to holding and distribution, including passive dewatering, as well as holding by-products at a particular temperature to facilitate transportation (e.g., keeping something in liquid or solid state).

Several sectors of the food industry have expressed concern about having to meet preventive controls requirements for certain other activities performed on their human food by-product and have asked that FDA consider streamlining the requirements for other activities that are also commonly performed to facilitate the storage and transportation of their by-products, including commingling ingredients, evaporating, chopping, mechanical mixing, pressing, trimming and washing.

The agency takes these concerns seriously and understands the practical value of these activities in preparing human food by-products for storage and transportation. As we implement FSMA requirements, we recognize the need to balance how these requirements impact current industry practices and the need to protect human and animal health. We are committed to working with industry to address these concerns, and are considering approaches that balance practical and public health considerations.

As we consider these approaches, the industry should be aware that in August 2017, we announced that we would not be conducting routine regulatory inspections of compliance with the animal food preventive controls requirements until the fall of 2018. This delay in routine regulatory inspections includes inspection of human food by-products that are further processed and required to comply with the animal food preventive control requirements.

## ***HUMAN FOOD USED IN PILOT PLANTS, TEST KITCHENS, RESEARCH & DEVELOPMENT***

**PC.21 Are facilities (such as pilot plants or test kitchens) that manufacture/process, pack, or hold food for research and development (R&D), consumer testing, or as food samples subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?**

In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States and that has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act is subject to the requirements related to preventive controls (primarily located in [subpart C](#) and [subpart G](#)) of the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#) (21 CFR part 117; 80 Fed. Reg. 55908) (CGMP & PC rule), unless subject to an exemption (see [21 CFR § 117.5](#) for exemptions). Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in [subpart B](#); those requirements are not dependent on whether a facility is required to register.

If a research and development (R&D)/pilot plant or test kitchen is a facility required to register (see [21 CFR § 1.225](#)), it will be subject to the requirements of the CGMP & PC rule, unless an exemption applies (see [21 CFR § 117.5](#) for exemptions).

Food used in R&D or as product samples is "food" for purposes of the food facility registration requirements of section 415 of the FD&C Act (see [21 CFR Part 1, subpart H](#)). Accordingly, a facility that manufactures/processes, packs, or holds food used in R&D or as product samples is required to register with FDA. However, if the food is not for consumption in the United States by humans or animals, the facility is not required to register (see [FDA's Guidance for Industry: Questions and Answers Regarding Food Facility Registration \(Seventh Edition\)](#), Answer to Question C.2.11: "Are facilities that manufacture/process, pack, or hold food used in research and development or as food samples required to register with FDA?")

If an R&D/pilot plant is not required to register with FDA, it is not subject to the requirements of [subpart C](#) (Hazard Analysis and Risk-Based Preventive Controls) and

[subpart G](#) (Supply-Chain Program) of the CGMP & PC rule. However, the R&D/pilot plant could still be subject to the requirements of [subpart B](#) (Current Good Manufacturing Practice (CGMP)) of the CGMP & PC rule.

## ***UNEXPOSED PACKAGED FOODS***

**PC.22 What are “Unexposed packaged foods”? Do unexposed packaged foods have to be in final packaged form ready for consumer purchase, or can they be ingredients that will be used in further processing to manufacture finished foods?**

“Unexposed packaged food” means packaged food that is not exposed to the environment (see [21 CFR § 117.3](#)). A food does not have to be packaged for a retail consumer (e.g., boxes of crackers or packages of chips) to be an unexposed packaged food. For example, an ingredient that will be used as a direct additive in food may be packaged in such a way that it meets the definition of “unexposed packaged food.” Unexposed packaged food is protected from outside bacteria by its packaging. See also the discussion in [Response 170](#) regarding produce packed in “vented crates,” which is not “unexposed packaged food.” (See [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#), [Response 170](#); 80 Fed. Reg. 55908 at 55970 (CGMP & PC Rule)).

## ***FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOODS***

**PC.23 If a facility is solely engaged in the storage of unexposed packaged food, is it exempt from the requirements for preventive controls?**

The [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#) ([21 CFR part 117](#); 80 Fed. Reg. 55908) (CGMP & PC rule) creates requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. In general, if a facility manufactures, processes, packs, or holds food for human consumption in the United States and has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (see [21 CFR Part 1, subpart H](#)), the facility is subject to the preventive controls requirements in the CGMP & PC rule, unless subject to an exemption. Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in [subpart B](#); those requirements are not dependent on whether a facility is required to register.

Subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of CGMP & PC rule do not apply to a facility **solely** engaged in the storage of unexposed packaged food (see [21 CFR § 117.7\(a\)](#)).

To qualify for the exemption, the facility storing the unexposed packaged food must be **solely** engaged in the storage of unexposed packaged food. For example, the exemption in § 117.7 would not apply to a facility that stores but also processes food (see CGMP & PC rule, [Response 212](#); 80 Fed. Reg. 55908 at 55985). Also note that unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in 21 CFR § 117.206.

**PC.24 Is a facility that is solely engaged in the storage of unexposed packaged food exempt from the requirements for preventive controls if some of the unexposed packaged food that is stored requires time/temperature control prevent or minimize pathogen growth?**

A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens **is subject to the modified requirements in [21 CFR § 117.206](#)** for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (see [21 CFR § 117.7\(b\)](#)). Thus, the modified requirements apply to the food that requires the time/temperature control.

## ***EXEMPTIONS TO THE PREVENTIVE CONTROLS RULE***

**PC.25 What exemptions from preventive controls are included in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?**

In general, a foreign or domestic facility that manufactures, processes, packs, or holds food for consumption in the United States and has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (see [21 CFR Part 1, subpart H](#)) is subject to the requirements related to preventive controls (primarily located in subparts C and G) of the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#) ([21 CFR part 117](#); 80 Fed. Reg. 55908) (CGMP & PC rule), unless subject to an exemption. Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in [subpart B](#); those requirements are not dependent on whether a facility is required to register. Also, the CGMP requirements may apply to facilities or food exempt from preventive controls (see 21 CFR 117.5(k) for exemptions from CGMPs).

The CGMP & PC rule contains the following exemptions or modified requirements related to preventive controls:

**Exemptions:**

- Activities subject to seafood HACCP (21 CFR Part 123) at a facility in compliance with seafood HACCP (21 CFR 117.5(b))
- Activities subject to juice HACCP (21 CFR Part 120) at a facility in compliance with juice HACCP (21 CFR 117.5(c))
- Activities subject to 21 CFR Part 113 (low acid canned foods) at a facility in compliance with part 113 (21 CFR 117.5(d)). This exemption is limited to microbiological hazards that are regulated under part 113.
- Manufacturing, processing, packaging, or holding a dietary supplement that is in compliance with certain requirements (21 CFR 117.5(e))
- Activities of a facility subject to the produce safety regulation in 21 CFR Part 112 (21 CFR 117.5(f))
- Certain low-risk on-farm activities on certain foods conducted by small or very small businesses (21 CFR 117.5(g) and (h)).
- Alcoholic beverages and prepackaged food at certain facilities that manufacture, process, pack, or hold alcoholic beverages (21 CFR 117.5(i))
- Facilities solely engaged in the storage or raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing (21 CFR 117.5(j))

***MODIFIED REQUIREMENTS***

**Modified Requirements:**

- Qualified facilities (21 CFR 117.5(a))
- Facilities solely engaged in the storage of unexposed packaged food (21 CFR 117.7). There are modified requirements applicable to these facilities for unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (21 CFR § 117.206).

# **FINAL RULE FOR PREVENTIVE CONTROLS FOR HUMAN FOOD AS IT RELATES TO DAIRY PRODUCTS PRODUCED UNDER THE PASTURIZED MILK ORDINANCE (PMO)**

## ***REQUIREMENTS UNDER PC RULE***

### **PMO.1. Do facilities operating under the PMO meet the requirements of the final preventive controls rule?**

The preventive controls provision of FSMA (section 103) does not exempt dairy facilities that are required to register with the FDA. The 2013 PMO does not address all of the FSMA requirements, such as a written hazard analysis, those relevant to food allergens, or the potential presence of environmental pathogens in the food processing environment. Such provisions in the Preventive Controls rule could help prevent food safety problems from the consumption of food produced in PMO facilities. At its biennial conference in April 2015, the National Conference on Interstate Milk Shipments (NCIMS) initiated work to modify the PMO; therefore we are extending the compliance date for PMO-regulated facilities to comply with the rule in order to make use of the existing system of state regulatory oversight for Grade “A” milk and milk products provided through the NCIMS and the food safety requirements of the PMO.

## **DAIRY FARMS**

### **PMO.2. Does the preventive controls rule apply to dairy farms?**

Establishments that meet the definition of a farm are not required to register under section 415 of the Food, Drugs, and Cosmetics (FD&C) Act. However, farms, including dairy farms, that conduct manufacturing/processing activities beyond those included in the farm definition in the Preventive Controls rule are subject to registration and would be subject to requirements of the Preventive Controls Rule unless a specific exemption applies.

## **PRODUCT TESTING**

### **PMO.3. What environmental and product testing for milk and dairy products is required under FSMA and the preventive controls rule?**

The Preventive Controls Rule includes requirements for environmental monitoring and finished product testing as verification activities that would be applied as appropriate to the food, the facility, and the preventive control. Such testing would be appropriate for certain ready-to-eat dairy products, e.g., environmental monitoring for *Listeria* spp. in facilities making soft cheeses that are exposed to the environment.

## **DIETARY SUPPLEMENTS**

### **ARE DIETARY SUPPLEMENT MANUFACTURERS EXEMPT FROM THE PREVENTIVE CONTROLS (PC) RULE?**

#### **DS.1 Is a manufacturer of dietary supplements exempt from the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?**

Dietary supplements are “food” as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act and is subject to the requirements related to preventive controls of the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#), unless subject to an exemption. An exemption for dietary supplements is provided in [21 CFR section 117.5\(e\)](#) which states that subparts C (hazard analysis and preventive controls requirements) and G (supply-chain program requirements) of 21 CFR part 117 do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of [21 CFR part 111](#) (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the FD&C Act (21 USC section 379aa-1) (Serious Adverse Event Reporting for Dietary Supplements).

### **ARE BULK DIETARY SUPPLEMENTS MANUFACTURERS EXEMPT FROM THE PC RULE?**

#### **DS.2 Is a manufacturer of bulk dietary supplements exempt from the preventive controls for human food?**

The exemption applies to finished dietary supplements in bulk form. For example, bulk finished dietary supplements that will be packaged or repackaged are exempt if in compliance with 21 CFR part 111 and 21 USC section 379aa-1.

## **ARE DIETARY INGREDIENTS EXEMPT FROM THE PC RULE?**

### **DS.3 Are dietary ingredients exempt from the preventive controls for human food rule?**

The exemption does not apply to the manufacturing, processing, packing, or holding of dietary ingredients. Dietary ingredients are subject to the requirements of the rule, including the current good manufacturing practice (CGMP) requirements of [21 CFR part 117, subpart B](#); the hazard analysis and risk based preventive controls requirements of [21 CFR part 117, subpart C](#); the supply chain program requirements of [21 CFR part 117, subpart G](#); and the recordkeeping requirements of [21 CFR part 117, subpart F](#).

## **REQUIREMENTS OF DIETARY SUPPLEMENT MANUFACTURERS UNDER THE PREVENTIVE CONTROLS RULE**

### **DS.4 Which Current Good Manufacturing Practice (CGMP) regulations apply to a manufacturer of dietary supplements, those in 21 CFR part 111 or those in 21 CFR part 117?**

A dietary supplement manufacturer would be required to comply with the CGMP regulations in [21 CFR part 117, subpart B](#) in addition to the regulations in [21 CFR part 111](#), unless the regulations conflict. To the extent regulations conflict, the manufacturer would comply with the regulation in [part 111](#) (see the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule, Response 197](#); 80 Fed. Reg. 55908 at 55978).

## **FOOD SAFETY PLANS**

### **FSP.1 My company has 3 separate food facilities. Are we required to have 3 distinct facility-specific food safety plans even though we produce the exact same food product at all 3 facilities?**

The overall framework of section 418 of the FD&C Act is directed to a facility. For example, section 418(b) of the FD&C Act provides in part that “[t]he owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards *that may be associated with the facility*” (emphasis added) (see the discussion of the facility-based nature of the food safety plan in the 2013 proposed rule; [78 Fed. Reg. 3646 at 3732](#)). Thus, the [Current Good Manufacturing Practice, Hazard Analysis,](#)

[and Risk-Based Preventive Controls for Human Food rule \(21 CFR part 117; 80 Fed. Reg. 55908\)](#) establishes a requirement for every facility to have its own written food safety plan (see [21 CFR § 117.126](#)). Even if a corporation makes or holds similar products at separate facilities, it is unlikely that the separate facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility including processing lines, technologies, and raw materials utilized as they will affect the approach to applying preventive controls such as allergen controls (see CGMP & PC rule, [Comment/Response 371](#)).

## FOOD PACKAGING MANUFACTURERS

### **FPM.1 Are food packaging manufacturers required to register with the FDA and comply with the preventive control requirements for Human Food?**

In general, subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule \(21 CFR part 117; 80 FR 55908\)](#)(CGMP & PC rule) apply to an establishment that is required to register with FDA as a food facility. **For purposes of registration, food-contact substances are not considered “food,” and therefore do not trigger the requirement to register** (see [21 CFR § 1.227](#)).

### **FPM.2 Are food packaging manufacturers required to create and maintain a Food Safety Plan?**

The manufacturing of **food packaging is not subject to subparts C (including the requirement for a food safety plan) and G of the CGMP & PC rule**. Other activities, such as placing food in the packaging, would require registration and be subject to subparts C and G, unless an exemption applies.

### **FPM.3 Do the Current Good Manufacturing Practices apply to a food packaging manufacturer?**

The CGMP regulations in [21 CFR part 117, subpart B](#) **apply to the manufacturing of food packaging**. These regulations address, among other things, the taking of adequate precautions to reduce the potential for allergen cross-contact and for

contamination of food, food-contact surfaces, and food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. Also, appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable (see [21 CFR § 117.80\(a\)\(2\)](#)).

## **PREVENTIVE CONTROLS FOR ANIMAL FOOD**

### ***REQUIREMENTS***

**PCAF.1 What are the major requirements under the final Preventive Controls for Animal Food regulation (21 CFR part 507)?**

The major requirements are listed in the fact sheet: [Preventive Controls for Animal Food At-A-Glance Fact Sheet](#) .

### ***ANIMAL FOOD DEFINITION***

**PCAF.2 What is animal food? What species does the Preventive Controls for Animal Food regulation cover? Does this include food for wild animals?**

“Food” is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include articles used for food or drink for man or other animals. The FD&C Act § 201(f) definition of “food” and the 21 CFR 507.3 definitions of “food” and “animal food” include articles used for components of food, such as raw materials or other ingredients. The PCAF rule applies to food for animals other than man. This includes, but is not limited to, companion (pet) animals, such as dogs, cats, and horses; and food-producing animals, such as cattle, pigs, and chickens. This also includes wild animals and minor species such as wild birds, deer, fish, hamsters, and honeybees.

### ***REGISTRATION***

**PCAF.3 How do I register as an animal food facility? If I am registered as a human food facility do I need a second registration?**

Information on food facility registration requirements and exemptions, and a link for registration, “FDA Industry Systems,” can be found at:

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities>

There is not a separate registration process for human and animal food. Your food facility registration must include applicable food product categories of any food manufactured/processed, packed, or held at a facility as identified on Form FDA 3537 (21 CFR 1.232(a)(7)). Also, if your facility's human food manufacturing results in by-product that you pack or hold for distribution as animal food, you must select the applicable animal food product categories for the by-products that you pack or hold.

Additional information on registration can be found in Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition) at:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition>

## ***CURRENT GOOD MANUFACTURING PRACTICES (CGMP) REQUIREMENTS***

### **PCAF.4 What current good manufacturing practice (CGMP) requirements do I need to follow for my animal food?**

Facilities that are required to register and that manufacture, process, pack, or hold animal food are subject to the CGMP requirements in 21 CFR part 507, [subpart B](#), unless an exemption applies. Exemptions to the CGMP requirements are found in [21 CFR 507.5\(a\) and \(h\)](#). Animal food covered by other specific CGMP regulations is also subject to the requirements of those regulations (21 CFR 507.1(c)). For example if you make medicated feeds, you will continue to be subject to the medicated feed CGMP requirements found in [21 CFR part 225](#). Likewise, if you make low-acid canned pet food, you will continue to be subject to the low acid-canned food CGMP requirements in [21 CFR part 113](#).

Additional guidance is available for animal food CGMPs. The Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals is available at:

<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf>.

**PCAF.5 How are the preventive controls rules different from the Hazard Analysis and Critical Control Points (HACCP) system?**

The Hazard Analysis and Critical Control Points systems that many FDA-regulated manufacturers have in place are the foundation of the preventive controls regulations. Although there are similarities between the preventive controls requirements and the HACCP system, not every provision is identical. For example, in HACCP systems, controls are applied at critical control points (CCPs), whereas preventive controls include controls at CCPs or controls other than those at CCPs that are appropriate for food safety.

**PCAF.6 My company has three separate food facilities. Are we required to have three distinct facility-specific food safety plans even though we produce the exact same food product at all three facilities?**

The overall framework is directed to a facility. Thus, the preventive controls final rules establish a requirement for every facility to have its own written food safety plan. Even if a corporation makes or holds similar products at separate facilities, it is unlikely that the separate facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility including processing lines, technologies, and raw materials utilized, as they will affect the approach to applying preventive controls.

**COMPLIANCE**

**PCAF.7 What are the compliance dates for the PCAF regulation for different size businesses?**

The compliance dates are as follows:

Business Size	CGMP compliance date	PC compliance date
Business other than small and very small	Sept. 19, 2016	Sept. 18, 2017
Small business (a business employing fewer than	Sept. 18, 2017	Sept. 17, 2018

Very small business (a business averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)).

Sept. 17, 2018

Sept. 17, 2019, except for records to support status as very small business (January 1, 2017)

For more information on compliance dates please see the [“FDA at a Glance, Key Requirements: Final Rule on Preventive Controls for Animal Food Fact Sheet.”](#)

Compliance dates for certain provisions of the PCAF rule were extended via another rule, [“The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance dates for Certain Provisions of Four Implementing Rules.”](#)

We also have announced our intent not to enforce certain regulatory requirements as they currently apply to certain entities and/or activities subject to the PCAF rule, via a guidance document, entitled [“Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.”](#) This policy is in effect while we consider amendments to the PCAF rule and other solutions to problems that have been identified.

#### **PCAF.8 When will routine inspections for compliance with the CGMP and preventive controls requirements begin?**

For information on the start of routine regulatory inspections for compliance with the PCAF regulation, please see FDA’s update on [“What to Expect with The Next Compliance Dates for the FSMA Preventive Controls for Animal Food Rule”](#) which was updated in August 2018.

### ***BUSINESS DEFINITIONS***

**PCAF.9 To determine whether my business is a “small business” do I count the total number of employees or just the ones specific to the animal food portion of my business?**

For purposes of this rule, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees is considered a small business.

FDA has made available [Draft Guidance for Industry: Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507](#). This draft guidance, when finalized, will explain FDA’s current thinking on this topic. The draft guidance includes the following Q/As:

**B.7 Should you account for employees that are not engaged in food activities covered by parts 117 or 507?**

Yes, all employees of the legal entity that includes the facility, as well as its subsidiaries and affiliates, should be counted regardless of whether they are engaged in covered food activities. Examples of non-food activities employees could be engaged in include retail operations, management, accounting, or marketing.

**A.3 What is a “subsidiary”?**

A “subsidiary” means any company which is owned or controlled directly or indirectly by another company (21 CFR 117.3 and 507.3). Note that only companies can have or be subsidiaries.

**A.4 What is an “affiliate”?**

An “affiliate” means any facility that controls, is controlled by, or is under common control with another facility (21 CFR 117.3 and 507.3). Only facilities required to register can be affiliates.

See also Q/A B.2 of the draft guidance, which describes how to determine the extent of a business.

**PCAF.10 In determining whether my business meets the definition of a “very small business,” what is the meant by the “applicable calendar year”?**

The applicable calendar year is the year after the three calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the three calendar years used to determine whether a facility is a very small business are 2021-

2023. The exception is when three calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations, the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

## ***QUALIFIED FACILITY***

### **PCAF.11 What are the requirements applicable to a qualified facility that manufactures, processes, packs, or holds animal food?**

A qualified facility is subject to requirements found in 21 CFR part 507, subpart B, Current Good Manufacturing Practices (unless an exemption applies). A qualified facility is exempt from subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and E (Requirements for a Supply-Chain Program) of part 507. A qualified facility must follow the requirements in 21 CFR 507.7.

Under 21 CFR 507.7, the qualified facility must submit two attestations to FDA: (1) an attestation that it is a qualified facility and (2) either an attestation that it has identified potential hazards, is implementing preventive controls to address the hazards, and is monitoring performance of the preventive controls or an attestation that the facility is in compliance with non-federal food safety laws and regulations.

If the facility selects the attestation that they are controlling the hazard, the facility must implement a preventive control for any hazards they identify requiring a preventive control and monitor (and document) the implementation of the preventive control (21 CFR 507.7(f)(1)). If the facility selects the attestation that they are in compliance with non-federal food safety laws or regulations, then the facility must follow the consumer notification requirement in 21 CFR 507.7(e).

The compliance date for a business meeting the definition of a “qualified facility” (including a “very small business”) is September 17, 2018 for the CGMP requirements and September 17, 2019 for compliance with 21 CFR 507.7. However, there is an earlier compliance date of January 1, 2017 for a facility to maintain (but not submit) financial records to support its status as a qualified facility.

December 16, 2019 is the date that animal food facilities must submit their initial attestations that the facility: (1) is a qualified facility and (2) has implemented food safety practices to control a hazard or that the facility is in compliance with non-federal food safety law.

More information is available in the following two guidance documents:

[Guidance for Industry #241, Small Entity Compliance Guide.](#)

[Guidance for Industry: Determination of Status as a Qualified Facility](#)

#### **PCAF.12 What form is used for qualified facility attestations?**

Form FDA 3942b is the attestation form for an animal food facility meeting the definition of a “qualified facility.” A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year. The attestations required must be:

- Submitted to FDA initially:
  - By December 16, 2019, for an animal food facility that begins manufacturing, processing, packing, or holding food before September 17, 2019;
  - Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019; or
  - By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination; and
- Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.
- When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination, the facility must notify FDA of that change in status by July 31 of the applicable calendar year.

Additional information on the qualified facility attestation form and Form FDA 3942b, including the final Guidance for Industry: Determination of Status as a Qualified Facility, can be found, at:

<https://www.fda.gov/food/registration-food-facilities/qualified-facility-attestation>.

### **PCAF.13 What records must be kept by a qualified facility regarding its attestations?**

There are records that a qualified facility is required to keep but does not need to submit to FDA as a part of their attestation (21 CFR 507.7(f)). These records include:

- Records to support your attestation that your facility meets the definition of a qualified facility (as defined in 507.3).
- Records that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or
- Records that your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. These records are subject to the record keeping requirements in [21 CFR part 507, subpart F](#).

## **EXEMPTIONS**

### **PCAF.14 Where do I find exemptions to the PCAF rule?**

The Preventive Controls for Animal Food (PCAF) rule applies to all facilities that are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they manufacture, process, pack, or hold animal food for consumption in the United States. Resources on whether a facility is required to register and how to complete the registration process can be found online at:

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities>. If you are not required to register, then you are exempt from the PCAF rule.

Exemptions to the PCAF rule for facilities that are required to register can be found in Title 21 of the Code of Federal Regulations section 507.5 ([21 CFR 507.5](#)). There are also modified requirements for storage of unexposed packaged food in 21 CFR 507.10 and holding certain human food by-products in 21 CFR 507.12.

You should also be aware that the FDA has published a [Guidance for Industry, “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.”](#)

This guidance describes certain activities or provisions for which the FDA is currently providing enforcement discretion with the intent to pursue rulemaking and other solutions to solving problems identified with these activities and provisions. Examples of facilities or provisions related to the PCAF regulation impacted by the enforcement discretion include:

- Facilities that would be farms except for certain factors and activities
- Written assurance provisions found in 21 CFR 507.36
- Animal food preventive control requirements for certain manufacturing/processing activities performed by human food manufacturers on their human food by-products used as animal food

## **WAREHOUSES**

### **PCAF.15 Are warehouses storing animal food subject to the PCAF rule?**

Warehouses are required to register because they are holding animal food and, thus, need to comply with the PCAF rule with respect to holding activities. This would include compliance with (1) the training requirements in 21 CFR 507.4; (2) the Current Good Manufacturing Practice (CGMP) requirements in 21 CFR part 507, subpart B; and (3) possibly the hazard analysis and risk-based preventive controls requirements in 21 CFR part 507, subpart C. The following exemptions/modified requirements may apply if your warehouse is solely engaged in the storage of unexposed packaged animal food:

- If your registered facility is solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, then your facility does not have to follow the hazard analysis and risk-based preventive controls provisions in 21 CFR part 507, subpart C and the supply-chain provisions in 21 CFR part 507, subpart E. (21 CFR 507.10)
- If your registered facility is solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that does require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, then your facility is subject to the modified requirements in 21 CFR 507.51.

Compliance with 21 CFR 507.51 (if applicable to your situation) and 21 CFR 507.4 requires certain records to be kept. These records are subject to the requirements of 21 CFR part 507, subpart F.

## ***RETAIL FACILITIES***

### **PCAF.16 Does my animal food business qualify as a retail facility? What exemptions apply for a retail facility?**

The term “retail food establishment” is defined as an establishment that sells food products directly to consumers as its primary function. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers (see 21 CFR 1.227).

To be considered a “retail food establishment” your annual monetary value of sales of food directly to consumers must exceed the annual monetary value of sales of food to all other buyers. The term “consumers” does not include businesses, such as farms. For example, a farm supply store may sell a variety of farm supplies, including selling animal food (e.g., livestock or poultry food) to farms and selling animal food (e.g., pet food) to end consumers. If more than 50% of the annual monetary value of sales of food is to consumers, such as pet owners and other individuals, then the farm supply store would meet the definition of a “retail food establishment” and would not be required to register. However, if more than 50% of the annual monetary value of sales of food is to other buyers, such as farms, then the farm supply store would not meet the definition of a “retail food establishment” and would be required to register.

We expect that animal food stores such as pet stores will likely meet the definition of a “retail food establishment” because their sales are primarily to consumers, such as pet owners. We expect that in most instances a farm supply store or feed retail store would not meet the definition of a “retail food establishment” because their sales are primarily to farms, which are considered businesses.

FDA’s [Guidance for Industry: Questions and Answers Regarding Food Facility Registration \(Seventh Edition\)](#) includes new Q&As about how the “retail food establishment” definition applies to animal food facilities, for example in question/answer B.2.18. If you are exempt from registration, you do not have to comply with the requirements in 21 CFR part 507.

## ***ANIMAL FOOD BROKERS***

### **PCAF.17 Do animal food brokers need to register?**

If you are a broker who does not manufacture, process, pack, or hold animal food, you are not required to register. FDA's understanding is that most brokers do not engage in manufacturing, processing, packing, or holding and furthermore, never take possession of the animal food. If you do manufacture, process, pack, or hold the food for consumption in the United States, you would be required to register your facility. Resources on whether a facility would be required to register and how to complete the registration process can be found online at:

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities>.

Establishments that are not required to register as food facilities are not required to follow the PCAF rule requirements found in 21 CFR part 507.

## ***TRAINING***

### **PCAF.18 Where can we go to get training and certification for the FDA Food Safety Modernization Act (FSMA) requirements?**

There is no certification for FSMA endorsed or developed by FDA. Many programs exist through trade associations that are best practices programs, but FDA does not have a certification process for FSMA. The current standardized curriculum that has been recognized by FDA as adequate training to meet the requirements for being a "preventive controls qualified individual" is the one developed and managed by the Food Safety Preventive Controls Alliance (FSPCA). Details on the FSPCA and course offerings can be found on the [FSPCA website](#).

## ***PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI)***

### **PCAF.19 What is a preventive controls qualified individual (PCQI)?**

A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

**PCAF.20 Do I need to employ a preventive controls qualified individual (PCQI)?**

If you are subject to the PCAF rule you are required to have a PCQI perform or oversee the development and implementation of your facility's food safety plan. The PCQI is not required to be an employee of the facility.

**PCAF.21 How does a PCQI demonstrate that he or she is qualified to serve as a PCQI?**

The preventive controls final rules specify that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

However, the rule does not require any specific certifications, including certification by the Food Safety Preventive Controls Alliance (FSPCA). An individual may voluntarily choose to attend the PCQI training provided through the FSPCA, but this is not mandatory. In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

**PCAF.22 I have many food safety certifications (HACCP, GFSI, SQF, BRC, etc.). Do I still need to take the PCQI training from the FSPCA?**

In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the PCAF rule, irrespective of documented training and experience.

There are some differences in the requirements of the PCAF rule compared to the requirements of HACCP regulations and other prevention-based food safety programs. As a result, the training provided by the International HACCP Alliance, GFSI, SQF, BRC, or other institutions might not be equivalent. In addition, there are differences in human food safety concerns versus animal food safety concerns that may not be equivalent. An individual should consider whether they need additional training specific to the PCAF regulation to understand how to implement an animal food safety system

that is compliant. However, the PCAF rule does not require any specific certifications, including certification by the FSPCA.

**PCAF.23 I have worked as a food safety manager for a very long time. Do I need to take PCQI training, or does my job experience satisfy the requirements to be a PCQI?**

Job experience may qualify an individual to develop and apply a food safety system, if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the PCAF rule, irrespective of documented training and experience. An individual should consider if they need additional training to appropriately address hazards for the animal species the facility's food is intended for.

**PCAF.24 Can I use one PCQI for all my facilities, or must I have one PCQI for each facility?**

The PCAF rule does not prohibit a company from utilizing the services of a single PCQI for multiple locations. Additionally, there are no restrictions on the proximity of the locations that are under the direction of any PCQI. You may want to consider if one PCQI will be capable of performing all of the required activities in 21 CFR 507.53 for all facilities, or if more than one PCQI will be needed.

**PCAF.25 Do I need a different PCQI for human food and human food by-products used for animal food? What animal food hazards need to be considered?**

Under the preventive controls requirements, a facility is required to conduct a hazard analysis in which they identify and evaluate any biological, chemical, or physical hazards that may be associated with the animal food or the facility. The PCQI is responsible for performing or overseeing the hazard analysis. A facility is not required to have a separate PCQI for animal food. However, the PCQI must be qualified to develop and apply a food safety system for the animal food.

FDA has made available draft [Guidance for Industry #239: Human Food By-Products for Use as Animal Food](#). When finalized, this draft guidance will explain FDA's thinking about human food by-products for use as animal food.

FDA also has made available draft [Guidance for Industry #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals](#). When finalized, this draft guidance will explain FDA's thinking on animal food hazards.

## ***ANIMAL FOOD USED AS BY-PRODUCT***

### **PCAF.26 What does the preventive controls for animal food rule specifically require human food facilities to do when providing a by-product for use as animal food?**

If the human food facility is in compliance with the human food current good manufacturing practice (CGMP) requirements and other applicable human food safety requirements and is not further manufacturing/processing the by-product, then they would only have to implement the additional limited CGMP requirements, found in either 21 CFR 117.95 or 507.28, to prevent contamination when holding and distributing the by-product. This is because they are already meeting human food safety requirements for operating their facility and for manufacturing/processing their human food up until the point where the by-product is generated. This regulation applies to human food facilities that both donate or sell a by-product for use as animal food. Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

If the facility is further processing a by-product for use as animal food (e.g., pelleting, heat-treatment to control pathogens), they would need to comply with CGMPs to help protect against contamination of the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product.

In addition, unless the facility is a qualified facility, exempt from subpart C (hazard analysis and preventive controls), or subject to enforcement discretion (see next paragraph), the facility would need to perform a hazard analysis to determine whether there are any hazards associated with the animal food that would require a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control would document such a determination in its hazard analysis but would not need to establish preventive controls.

Note that we are exercising enforcement discretion with regard to the preventive controls requirements for certain manufacturing/processing activities performed by human food manufacturers on their human food by-products for use as animal food.

Your facility may fall under the FDA enforcement discretion policy if you conduct certain manufacturing activities to reduce weight, bulk, or volume or conduct certain activities to combine by-products or separate components and these activities are not intended to control hazards. For more information see Section III.D (pages 19-20) of Guidance for Industry “[Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.](#)”

Additionally, FDA has made available draft [Guidance for Industry #239: Human Food By-Products for Use as Animal Food](#). When finalized, this draft guidance will explain FDA’s current thinking on facilities that produce both human and animal food, including human food by-products for use as animal food.

**PCAF.27 Do the PCAF requirements apply if I donate or barter human food by-products rather than selling them?**

The PCAF requirements (21 CFR part 507) apply to all facilities that are required to register with the FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they manufacture, process, pack, or hold animal food for consumption in the United States. Therefore, if a facility is manufacturing, processing, packing, or holding animal food for consumption in the U.S., then they are expected to register and comply with the PCAF requirements, even if they donate or barter the animal food instead of selling it.

**PCAF.28 Do the PCAF requirements apply if I am a grocery or other retail store that is donating or selling human food by-products for use as animal food.**

If you meet the definition of a retail food establishment and are exempt from registration, you would not have to meet the PCAF requirements (21 CFR part 507). However, that does not mean that you do not have any animal food safety obligations. As a general matter, firms, including those exempt from registration, must not introduce for delivery into interstate commerce any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

# FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

## ***IMPORTER RESPONSIBILITY***

### **FSVP1: I operate a facility in a foreign country. What is my responsibility under FSVP?**

The regulation on Foreign Supplier Verification Programs (FSVP) (21 CFR part 1, subpart L (sections 1.500-1.514)) applies to U.S. importers of food. However, importers may request information from their foreign suppliers or others to meet their FSVP requirements.

Standard FSVP requirements include, but are not limited to,

- conducting hazard analyses for imported food ([section 1.504](#)),
- evaluating the food and the foreign supplier ([section 1.505](#)),
- determining and performing supplier verification activities ([section 1.506](#)),
- taking corrective actions (when necessary) ([section 1.508](#)),
- ensuring importer identification at entry ([section 1.509](#)), and
- maintaining records ([section 1.510](#)).

In general, the importer will need to obtain assurances that its supplier is producing food using processes and procedures that provide the same level of public health protection as those required under the preventive controls requirements in [21 CFR part 117](#) or [507](#) or under the produce safety regulation ([21 CFR part 112](#)), as well as assurances that the food is not adulterated and not misbranded with respect to allergen labeling (section 1.502(a)).

The FSVP importer of a food might choose to rely on others to conduct certain FSVP activities, provided the importer reviews and assesses the results of these activities (see, e.g., sections 1.504(d), 1.505(d), 1.506(d)(3) and I(2)). For example, an importer may rely on a hazard analysis of a food conducted by the foreign supplier, and an importer might rely on the results of an independent third-party audit of the supplier that the supplier has requested.

Supplier verification activities must provide assurances that the hazards requiring a control in a food have been significantly minimized or prevented (section 1.506I). Depending on what verification activities the importer conducts, the importer might request information from the foreign supplier, such as results of audits or copies of relevant food safety records, so that it can meet its verification requirements.

### **FSVP2: Who is the importer under FSVP?**

For the purposes of FSVP, the definition of the term “importer” is the “U.S. owner or consignee” of an article of food offered for import into the U.S. This is the person in the United States who, at the time of entry of an article of food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulation. ([See 21 CFR 1.500.](#))

There are a variety of commercial arrangements regarding the importation of food. In some cases, one or more persons may have purchased the food (i.e., obtained it through payment of money or equivalent) or agreed in writing to purchase the food but do not own it at the time of entry. In addition, there may be cases in which, although ownership of an imported food has not transferred from the foreign owner at the time of the food’s entry into the United States, there are one or more U.S. entities who have purchased the food or agreed in writing to purchase it.

**FSVP3: Is the “importer” under the FSVP rule the same as the “importer of record” recognized by U.S. Customs and Boarder Protection for import entry?**

The importer of record (as defined by CBP) may be the same as the importer under FSVP, but is not necessarily.

The FSVP Importer performs certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. In contrast, the CBP importer of record of a food might be an express consignment operator with little to no knowledge of the safety regulations applicable to the products for which they obtain clearance from CBP.

## **RECORDS**

**FSVP4: I am a very small importer. Do I need to keep FSVP records, and send them to FDA? If so, what is the best way to notify FDA?**

As a very small importer subject to the FSVP rule, you are required to keep FSVP records in accordance with [21 CFR 1.512\(b\)\(5\)](#). However, you are not required to send your records to FDA unless FDA requests, in writing, that you send your records (see [21 CFR 1.512\(b\)\(5\)\(ii\)\(C\)](#)). (FDA may also request you to make your records available for inspection and copying at your place of business ([see 21 CFR 1.512\(b\)\(5\)\(ii\)\(A\)](#))).

As specified in [21 CFR 1.512\(b\)\(5\)\(i\)\(A\)](#), you must keep FSVP records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm,

microfiche, or other accurate reproductions of the original records), or electronic records. You must sign and date your records upon initial completion and upon any modification ([21 CFR 1.512\(b\)\(5\)\(i\)\(B\)](#)). All required records must be legible and stored to prevent deterioration or loss ([21 CFR 1.512\(b\)\(5\)\(i\)\(C\)](#)) You must retain your FSVP records for at least 2 years after you created or obtained the records ([21 CFR 1.512\(b\)\(5\)\(iii\)\(A\)](#)). However, with respect to records that support your status as a very small importer, you must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year ([21 CFR 1.512\(b\)\(5\)\(iii\)\(C\)](#)).

Offsite storage of records, including records maintained by other entities in accordance with the FSVP regulation is permitted if the records can be retrieved and provided onsite within 24 hours of request for official review ([21 CFR 1.512\(b\)\(5\)\(ii\)\(B\)](#)). Electronic records are onsite if they are accessible from an onsite location ([21 CFR 1.512\(b\)\(5\)\(ii\)\(B\)](#)).

If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business ([21 CFR 1.512\(b\)\(5\)\(ii\)\(C\)](#)).

For more information on the FSVP regulation, see our [FSVP web page](#)

**FSVP5: I import food from very small foreign suppliers. Do I need to keep FSVP records, and send them to FDA? If so, what is the best way to notify FDA?**

You are required to keep FSVP records, but are not required to send them to FDA unless FDA requests, in writing, that you send your records ([see 21 CFR 1.512\(b\)\(5\)\(ii\)\(C\)](#)). (FDA may also request you to make your records available for inspection and copying at your place of business ([see 21 CFR 1.512\(b\)\(5\)\(ii\)\(A\)](#))).

As specified in [21 CFR 1.512\(b\)\(5\)\(i\)\(A\)](#), you must keep FSVP records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. You must sign and date your records upon initial completion and upon any modification ([21 CFR 1.512\(b\)\(5\)\(i\)\(B\)](#)). All required records must be legible and stored to prevent deterioration or loss ([21 CFR 1.512\(b\)\(5\)\(i\)\(C\)](#)).

If requested, you must make all records required under this subpart ([21 CFR 1.510](#)) available promptly to an authorized FDA representative for inspection and copying. Upon FDA request, you must provide an English translation of records maintained in a language other than English within a reasonable time ([21 CFR 1.512\(b\)\(5\)\(ii\)\(A\)](#)).

Offsite storage of records, including records maintained by other entities in accordance with the FSVP regulation, is permitted if the records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are onsite if they are accessible from an onsite location. ([see 21 CFR 1.512\(b\)\(5\)\(ii\)\(B\)](#))

If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business ([21 CFR 1.512\(b\)\(5\)\(ii\)\(C\)](#)).

For more information on the FSVP regulation, see our [FSVP web page](#).

## ***ALCOHOLIC BEVERAGE IMPORTS***

### **FSVP6: What FSVP requirements apply to alcoholic beverages I import?**

Importers of alcoholic beverages are exempt from the regulation on foreign supplier verification programs (FSVP) if the requirements in 21 CFR 1.501I are met.

## ***FOREIGN SUPPLIER VERIFICATION REQUIREMENTS***

### **FSVP7: What do I need to do to verify my foreign supplier is following the FSVP rule?**

Importers covered by (FSVP) must have a program in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls requirements for human and animal food under section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the produce safety requirements under section 419 of the FD&C Act , if applicable, and the implementing regulations, and to ensure that the food is not adulterated and is not misbranded with respect to allergen labeling. Standard FSVP requirements include determining known or reasonably foreseeable hazards with each food; evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance; using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities; conducting supplier verification activities; and conducting corrective actions, as appropriate. Modified requirements may apply in some circumstances ([see 21 CFR 1.500-1.514](#)).

Verification activities under FSVPs may include reviewing food safety records, onsite inspections, and testing and sampling shipments of imported products, among other appropriate supplier verification activities ([see 21 CFR 1.506\(d\)\(1\)\(ii\)](#)).

## ***FOOD CONTACT SUBSTANCES UNDER FSVP***

### **FSVP8: Are imported food contact substances subject to FSVP? If so, when does the regulation start?**

The importation of food contact substances is subject to the FSVP regulation, but on January 4, 2018 FDA announced that it intends to exercise enforcement discretion for FSVP requirements for importers of food contact substances. This means that the agency does not intend to enforce FSVP requirements for food contact substances.

However, importers of food contact substances remain subject to the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a)).

For information concerning food contact substances, please see our web page titled [Packaging & Food Contact Substances](#).

For more information on the FSVP regulation, please see our [FSVP web page](#)

## ***USDA REGULATION EXEMPTIONS***

### **FSVP9: Are foods that are subject to USDA regulation exempt from FSVP?**

The FSVP regulation does not apply to certain meat, poultry, and egg products that at the time of U.S. entry are subject to USDA regulation, as follows (see 21 CFR 1.501(h)):

- Meat food products that, at the time of importation, are subject to the requirements of USDA under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.).

The FMIA regulates the inspection of the following species: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. In addition, under the FMIA, the USDA regulates fish of the order Siluriformes and products derived from these fish. Food from other animals (e.g., bison, rabbits, game animals, and all members of the deer family including elk (wapiti) and moose) is not subject to the requirements of the FMIA at the time of importation and therefore would be subject to FSVP. In addition,

products with 3 percent or less raw meat; less than 2 percent cooked meat or other portions of the carcass; or less than 30 percent fat, tallow or meat extract, alone or in combination; and closed-face sandwiches are not subject to the requirements of the FMIA at the time of importation and therefore would be subject to FSVP.

- Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.).

The PPIA defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas, ratites and squab. Products containing either less than 2 percent cooked poultry meat; or less than 10 percent cooked poultry skins, giblets, fat and poultry meat (limited to less than 2 percent); and closed-face sandwiches are not subject to the requirements of the PPIA at the time of importation and therefore would be subject to FSVP. In addition, food from all non-specified birds, including wild turkeys, wild ducks, and wild geese, is not subject to the requirements of the PPIA at the time of importation.

- Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.).

Egg products are made from the shell eggs of domesticated chicken, turkey, duck, goose or guinea. USDA defines “egg product” to include dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. Note that egg products do not include shell eggs. Also, egg products do not include, among other foods: egg substitutes, cooked egg products, freeze-dried products, imitation egg products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies.

For more information on meat, poultry, and egg products subject to USDA regulation at the time of importation, see [Imported Food Products Containing a Small Amount of Meat, Poultry, or Processed Egg Product Ingredients](#).

## ***INDUSTRY TRAINING***

### **FSVP10: Where do I find information about industry training for FSVP?**

The Food Safety Preventive Controls Alliance (FSPCA) is developing training regarding supplier verification that will be available to importers who are subject to the FSVP

regulation. Please refer to the links below for additional information regarding FSMA training and the FSPCA.

Please note, however, that importers will not be required to have their qualified individuals who perform FSVP activities take the FSPCA training (or any other particular training) when it becomes available. Importers may rely on training on supplier verification (and related FSVP activities, such as hazard analysis) that is available from other sources to ensure that persons conducting FSVP activities for the importer have the necessary education, training, or experience (or a combination of those factors) to perform a particular activity required by the FSVP regulation (see 21 CFR 1.503). In addition, it might also be possible for a person to obtain the necessary expertise to serve as a qualified individual through experience or education.

For additional information please visit:

[The FSMA Training Strategy webpage](#)

[The Food Safety Preventive Controls Alliance \(FSPCA\) website](#)

#### **FSVP11: How do I become an FSVP trainer?**

FDA does not offer FSVP training programs. However, the Food Safety Preventive Controls Alliance (FSPCA) has developed training curricula for persons who are subject to the FSVP regulation or who want to understand the requirements; and for persons interested in becoming lead instructors. For more information, see [the FSPCA website](#)

### ***DATA UNIVERSAL NUMBERING SYSTEM (DUNS NUMBER)***

#### **FSVP12: What is a DUNS #? Where do I get one?**

The FSVP regulation requires that an importer provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States (21 CFR 1.509(a)). The FDA has [recognized the Data Universal Numbering System \(DUNS\) number as an acceptable UFI for FSVP.](#)

DUNS numbers are assigned and managed by Dun & Bradstreet. They can be obtained by either emailing [govt@dnb.com](mailto:govt@dnb.com) or calling 1-800-234-3867, which is specifically designed for FDA-related inquiries. An FSVP Importer can obtain the DUNS number free of charge (charges may apply for expedited service).

## **RESOURCES**

### **FSVP13: What resources are available for FSVP?**

Several resources related to FSVP are listed below.

[FSVP webpage](#)

[FSVP Q & As](#)

[The 'Am I Subject to FSVP' flow diagram](#)

[The FSMA Training Strategy webpage](#)

[The Food Safety Preventive Controls Alliance](#)

## **COMPLIANCE DATES**

### **FSVP14: What are the compliance dates for FSVP? What is the Compliance Date for a small importer?**

The earliest that an importer would need to comply with the FSVP regulation would be 18 months after issuance of the final rule, i.e., May 2017. Importers whose foreign supplier must comply with the following rules will be required to comply with the FSVP regulation six (6) months after their supplier is required to comply with the applicable regulation. The regulations are as follows:

[Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,](#)

[Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,](#) or

[Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.](#)

For further information, please visit our webpage for [FSVP Compliance Dates](#).

## **SYSTEM RECOGNITION**

### **FSVP15: I am searching for the list of those countries currently approved as “Equivalent Countries” for the purpose of the F.S.V.P.**

Currently, New Zealand, Canada and most recently Australia are the only countries that have signed Systems Recognition arrangements with FDA. For the purposes of importers availing themselves of the modified FSVP requirements for foods from these countries, the importer must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination. For clarification, FDA's Systems Recognition program is not the same as equivalence. The term "equivalence" is used principally in the context of the international trading regime established under the World Trade Organization and in other free trade agreements, such as the North American Free Trade Agreement.

Systems recognition is voluntary and not required in order for a country to export foods to the U.S. The FDA continues to have inspection authority over food imported from any country with which it has an arrangement and can exercise this authority as needed. Imports from countries that have signed Systems Recognition arrangements with FDA must continue to comply with U.S. statutory and regulatory requirements to ensure safety and proper labeling, including the new standards adopted under the [FDA Food Safety Modernization Act](#).

**FSVP16: I import products from a country that has a systems recognition agreement with the US. Do I still need to verify that my supplier meets FDA food safety requirements?**

Under the [Foreign Supplier Verification Programs for Importers of Food for Humans and Animals rule](#) (21 CFR part 1, subpart L; 80 Fed. Reg. 74226) (FSVP rule), importers are required to perform certain risk-based activities to verify that the food they import into the United States has been produced in a manner that meets applicable U.S. safety standards. Standard FSVP requirements include, but are not limited to, conducting hazard analyses for the imported food; evaluating the risk posed by a food and the foreign supplier's performance; approving suppliers; conducting supplier verification activities; taking corrective actions (when necessary); ensuring importer identification at entry; and maintaining records. The United States and certain countries have entered into Food Safety Systems Recognition arrangements and, therefore, importers of certain foods from foreign suppliers located in those countries who are in good compliance standing with those authorities are not required to comply with these standard FSVP requirements. Instead, they can follow modified FSVP requirements in 21 CFR 1.513 if the food they import is not intended for further manufacturing/processing (21 CFR 1.513(a)(2)). If the food is not intended for further manufacturing/processing and the importer chooses to follow these modified requirements, the importer must document that the foreign supplier is in, and under the regulatory oversight of the recognized foreign food safety system, and must determine

and document whether the foreign supplier of the food is in good compliance standing with the food safety authority (21 CFR 1.513(b)(1)-(2)).

Importers of certain foods from foreign suppliers located in an officially recognized or equivalent food safety system must comply with the following sections:

- [1.503](#) – Who must develop my FSVP and perform FSVP activities?
- [1.509](#) – How must the importer be identified at entry?
- [1.510](#) – How must I maintain records of my FSVP?
- [1.513](#) – Requirements as stated in section 1.513

The FSVP requirements for food imported from foreign suppliers located in countries with comparable or equivalent systems only applies to a food **not intended for further manufacturing or processing, which includes packaged food products and raw agricultural commodities not intended to be commercially processed further before consumption, and the food must be within the scope of the country's official recognition or equivalency determination.**

A systems recognition arrangement (SRA) between the U.S. and another country may not cover all foods produced in each country, but will typically cover many different types of food (rather than particular commodities).

## THIRD PARTY ACCREDITATION (TPP)

### AUDITS

#### TPP.1 How will the third-party certification program work?

The final rule establishes a system for the FDA to recognize accreditation bodies that in turn accredit third-party certification bodies to perform food safety audits and issue certifications for foreign food facilities and the foods they produce. Such certifications will be required for participation in the Voluntary Qualified Importer Program (VQIP), which will allow for expedited review and entry of foods from importers in the program. In addition, to prevent potentially harmful food from reaching U.S. consumers, the FDA can require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

#### TPP.2 What are the key features of the program?

More information about the final rule can be found in the [Third Party Accreditation At-a-Glance](#) fact sheet.

#### TPP.3 Will certification bodies have to submit their audit reports to FDA?

For regulatory audits, in which a facility is examined for compliance with FDA food safety requirements for purposes of certification, an accredited third-party certification body must routinely submit an audit report to the FDA. For consultative audits, which are performed in preparation for regulatory audits and do not result in issuance of a certification, the audit report is generally intended for internal use. The FDA must be notified if a potential serious risk to public health is identified during a regulatory or consultative audit.

**TPP.4 Can a foreign government serve as a third-party certification body?**

Yes. Public and private agencies and organizations are eligible for accreditation as third-party certification bodies.

**TPP.5 Can reports and notifications from participants in this program be submitted in their native language?**

No, all reports and notifications required to be submitted to the FDA must be submitted in English to be properly and efficiently reviewed.

**TPP.6 How long does recognition (i.e., qualification) last for recognized accreditation bodies?**

The FDA may grant a period of recognition for an accreditation body of up to five years. The length of recognition granted will be determined on a case-by-case basis, depending on a number of factors, including the accreditation body's experience conducting accreditation work in the food safety area.

**TPP.7 How long does the accreditation last for certification bodies?**

The maximum duration of accreditation for certification bodies is four years under the rule.

**TPP.8 Can both foreign and domestic food entities receive food safety audits conducted under the Accredited Third-Party Certification program?**

Only foreign food entities can receive food safety audits under the third-party certification program. The program does not apply to audits of domestic firms.

***APPLICATION SUBMISSION***

**TPP.9 Where do I submit an application to participate in this program?**

The Accredited Third-Party Certification rule that FDA issued on November 27, 2015 establishes the framework, procedures, and requirements for the program.

An accreditation body recognized by FDA under this program could be a foreign government/agency or a private third party. Accreditation bodies assess third-party certification bodies for accreditation and monitor their performance.

Third-party certification bodies will be accredited under this program to conduct food safety audits and to certify that foreign food facilities, and the foods they produce, meet FDA food safety standards.

FDA issued two companion documents in December 2016. First, FDA issued a guidance to industry entitled, "[Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards](#)," which contains FDA recommendations on third-party certification body qualifications. Second, FDA issued a final rule entitled, "[Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications to Provide for the User Fee Program](#)," which provides for a user-fee program to assess fees and require reimbursement for the work the agency performs to establish and administer the third-party certification program.

In June 2017 FDA [launched a website](#) where organizations can apply to be recognized as an Accreditation Body. Third-party certification bodies can seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

Once recognized by FDA, an accreditation body may begin accrediting third-party certification bodies that meet our program requirements.

More information including a [Fact Sheet on the Final Rule on Accredited Third-Party Certification](#) may be found on our [website](#).

## ***ACCREDITATION BODIES***

### **TPP.10 Where do I find a list of accreditation bodies?**

FDA's Accredited Third-Party Certification Program is now operational. FDA opened the portal to accept applications in January 2018. The agency has begun accepting applications from accreditation bodies for participation in the program. Once recognized by FDA, an accreditation body may begin accrediting third-party certification bodies that meet our program requirements.

The FDA maintains a public registry of recognized accreditation bodies. The public registry includes a list of the names and contact information for the FDA-recognized accreditation body, along with other information. A complete list of accreditation bodies

that have been recognized under the program may be found here:

<https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program-public-registry-recognized-accreditation-bodies>

More information, including a [Fact Sheet on the Final Rule on Accredited Third-Party Certification](#), may be found on our [website](#).

# **VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP)**

## ***GENERAL INFORMATION***

### **VQIP.1 Where do I get more information about VQIP?**

VQIP is a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains.

On November 10, 2016, FDA posted final guidance in a question-and-answer format to explain how this program works.

More information about FDA's Voluntary Qualified Importer Program (VQIP) is available online at the following link: <https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip>

The link contains information such as:

- [Final Guidance for Industry: FDA's Voluntary Qualified Importer Program](#)
- [Final Guidance Fact Sheet](#)
- [Instructions for Submitting the VQIP Application](#)
- [Webinar on the Final Guidance for the Voluntary Qualified Importer Program](#)
- [Federal Register Notice](#)

### **VQIP.2 When did VQIP begin?**

The FDA began accepting applications in January 2018. VQIP benefits will begin October 1 following your acceptance into the program and will last through September 30 of the following year (VQIP year). More information about FDA's Voluntary Qualified Importer Program (VQIP) is available online at the following link:

<https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program->

The link contains information such as:

- [Final Guidance for Industry: FDA's Voluntary Qualified Importer Program](#)
- [Final Guidance Fact Sheet](#)
- [Instructions for Submitting the VQIP Application](#)
- [Webinar on the Final Guidance for the Voluntary Qualified Importer Program](#)
- [Federal Register Notice](#)

### **VQIP.3 How do I communicate with FDA about my VQIP application?**

The VQIP Importers Help Desk is available to assist with the application process and/or answer questions from the import trade community, other government agencies, or FDA staff between 8am & 8pm EST via phone at 1-301-796-8745 or email

[FSMAVQIP@fda.hhs.gov](mailto:FSMAVQIP@fda.hhs.gov).

## **COMPLIANCE**

### **VQIP.4: How will VQIP fees be determined?**

FSMA requires that the fees be based on an estimate of 100 percent of the costs of the program. These include the costs of reviewing an anticipated 200 applications; the costs of conducting inspections of importers (both foreign and domestic) accepted into the program; and the annual Information Technology (IT) maintenance costs. A [June 2015 Federal Register notice](#) projected a preliminary estimate of \$16,400 as the user fee to be paid by each VQIP participant in the first year of the program. This estimate was based in part on the significant cost of conducting inspections; inspection hourly rates are established for each Fiscal Year and adjusted for inflation. For reference, the [Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2018](#) established a general hourly rate of \$231, a domestic hourly rate of \$248, and a foreign hourly rate of \$285.

## **SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD UPDATED 2018**

### **RECORDS FOR CARRIERS**

**ST2018.1 Could you please clarify which records needed to be carried on the carrier's person?**

The [Sanitary Transportation of Human and Animal Food](#) (ST rule) does not require the carrier to carry any specific documentation. Please review the [records requirements in the rule](#). When 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, *carriers* covered by the rule and who are responsible for sanitary conditions during food transportation are required to meet the requirements in section [1.908\(e\)](#) of the rule. For example, this includes that, if requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that

identifies the previous cargo transported in the vehicle, or must provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

## ***QUALIFIED INDIVIDUAL***

### **ST2018.2 What is the meaning of Qualified Individual?**

For information on qualified individual, please read [comment/response # 129](#) and [comment/response # 162](#) in the ST rule.

## ***SEAFOOD FARMS***

### **ST2018.3 The ruling states that farms, including "seafood farms," are exempt, but, for example, the transport of live molluscan shellfish is not. How would live oysters that are farm raised fit into this category?**

Transportation activities performed by a farm are not subject to the ST rule per the exclusion in the definition of "[Transportation operations](#)". Therefore, if your entity meets the definition of a "farm" in [21 CFR 1.227](#), then the "transportation activities" it performs would not be subject to the rule. Please read [Comment/Response # 79](#) for discussion on transportation activities performed by a farm. Non-farm carriers (for example, another party hired for transportation) are subject to this rule, unless they are non-covered or exempt. Please read [Comment/Response # 83](#) for more information. Businesses that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program (NSSP), only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority, are waived from the requirements of the ST rule. If seafood farms do not meet the requirements of the [Waiver](#), then they are subject to the requirements of the ST rule. Please see [comment/response 78](#).

## ***TRAINING***

**ST2018.4 Are there any certified agencies that can provide training for the ST Rule?** There are no certification requirements for companies providing training on the ST rule. Carriers covered by the rule may choose to develop their own training, use [FDA's training module](#) (provided at no cost), or use training offered by a third party. The training module offered by FDA touches on a wide range of transportation food safety topics in a fairly cursory manner. FDA anticipates that many carriers will wish to provide

additional training that focuses on company-specific operations and procedures related to food safety.

## ***REGISTRATION***

### **ST2018.5 Do I need to register under the ST rule?**

The ST Rule does not require shippers, loaders, carriers, or receivers to register with the FDA. However, there are registration requirements established under the Public Health Security and Bioterrorism Preparedness and Response Act and the FDA Food Safety Modernization Act, which require [certain food facilities to register with the FDA](#).

## ***CO-HAULING FOOD & NON-FOOD ITEMS***

### **ST2018.6 Is it okay to ship food and non-food items together in the same load?**

The ST Rule does not prohibit the transport of food and non-food items in the same load. However, as stated in [comment/response #105](#), cross utilization of vehicles should not subject any food to cross contamination during transport. The provisions of § 1.906 require the design, maintenance and storage of vehicles and transportation equipment, to be such that they will not cause food to become unsafe during transportation operations. In addition, [§ 1.908\(a\)\(3\)](#), which in part addresses the proper use of vehicles and equipment in transportation operations, requires that all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe.

## ***TRUCK SEALS***

### **ST2018.7 Do trucks/containers transporting foods not exempt under the ST rule, need to be sealed/locked during transportation?**

The ST Rule does not require that trailers hauling food products be sealed during transit. [We stated in the final rule that routine security measures, such as the use of truck seals, are beyond the scope of the rule.](#) We also addressed what measures entities subject to the rule should take if they observe evidence of tampering during transportation operations ([see comment/response 46](#)). Further, if a party subject to the ST rule becomes aware of conditions that may render the food unsafe during transportation, the rule requires that the food not be sold or otherwise distributed unless a determination is made by a qualified individual that the condition did not render the food unsafe.

Additionally, [the Mitigation Strategies To Protect Food Against Intentional Adulteration rule \(21 CFR Part 121; 81 Fed. Reg. 34166\)](#) (IA Rule) does not include requirements for carriers. The IA Rule applies to the owner, operator or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 USC 350d) unless subject to an exemption (see [21 CFR 121.5](#) for exemptions). The IA Rule requires covered facilities to prepare, or have prepared, and implement a [written food defense plan](#) that includes a (1) written vulnerability assessment, including required explanations, to identify significant vulnerabilities and [actionable process steps](#); (2) written mitigation strategies including required explanations; (3) written procedures for the food defense monitoring of the implementation of the mitigation strategies; (4) written procedures for food defense corrective actions; and (5) written procedures for food defense verification ([21 CFR 121.126](#)). If a facility identifies an actionable process step associated with transportation, the facility must identify and implement mitigation strategies to significantly minimize or prevent the significant vulnerability associated with that actionable process step ([21 CFR 121.135](#)). [Based on our vulnerability assessments, we determined that the most practical mitigation strategies to ensure the integrity of food during transport would be implemented by facilities, rather than by carriers. For example, to significantly minimize or prevent a food from being intentionally adulterated during transport, a shipper may elect to use seals to secure access points, such as doors or hatches, on the transport conveyance.](#) If a facility chooses to use seals as a mitigation strategy, and the seals are found to be broken, the facility is required to implement corrective actions ([21 CFR 121.145](#)). The IA Rule does not require a particular disposition of food when a mitigation strategy is found to be improperly implemented. Note that the compliance dates for the IA Rule depend on business size and begin on July 26, 2019.

## **REGULATORY AUTHORITY**

### **ST2018.8 Do the Department of Transportation (DOT) and USDA requirements supersede FDA regarding sanitary transportation of food?**

Congress enacted the 2005 Sanitary Food Transportation Act to grant FDA, DOT, and USDA shared responsibility over regulating the sanitary transportation of food. While DOT has authority to conduct transportation safety inspections for identifying suspected incidents of food shipments that are not in compliance with this rule and is authorized by section 416(f) of the FD&C Act to provide assistance upon request from FDA in the enforcement of this rule, FDA will generally be responsible for taking action when food

or persons are found to be in violation of the statutes and regulations it administers. See [Response 19](#) of the Sanitary Transportation Rule.

## ***USDA-REGULATED PRODUCTS***

### **ST2018.9 Does the final ST rule apply to foods that are typically regulated by USDA, meaning beef, pork, poultry, etc.?**

The extent of the applicability of the rule under the circumstances does not depend on the type of food, but whether the United States Department of Agriculture has exclusive jurisdiction throughout the entire facility. Per section [1.900\(b\)\(3\)](#), the provisions of the rule do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations of food when it is located in food facilities that are regulated exclusively, throughout the entire facility, by USDA under Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). If the facility is under dual jurisdiction, then FDA would inspect in accordance with its existing MOU with USDA. Please read [Comment/Response #12](#) for further discussion on this topic. It should be noted that once a shipment of any such food has left the facility, the operation is subject to the requirements of the ST rule.

## ***“COMPLETELY ENCLOSED CONTAINER”***

### **ST2018.10 What is a “completely enclosed container”? Am I subject to the ST rule if I solely transport completely enclosed containers?**

The transportation of food completely enclosed by its container that **does not** require temperature control for safety is not subject to the ST rule per the exclusion in the definition of “[Transportation operations](#)”. Under the rule, a completely enclosed container is one that physically separates the food from the environment and functionally protects it from environmental contamination during transportation. Please see [Comment/Response # 59](#) and [Comment/Response #60](#) in the ST rule for information about the meaning/examples of completely enclosed by a container. For example, a container can be a tote, a cardboard box, a plastic bag/box, a metal can, a glass/plastic bottle, or a bin. If you transport only food that is completely enclosed and does not require temperature control for safety, you are not subject to the ST rule.

## **CLEANING & SANITIZATION REQUIREMENTS**

### **ST2018.11 Are there specific sanitation methods for trailers required under the ST rule?**

The ST Rule does not provide requirements for products used to clean vehicles/transportation equipment. There are no provisions in the rule that establish requirements for how trucks are to be cleaned/sanitized. FDA has not established SOPs, sanitation guidelines, or requirements for cleaning in the rule. The parameters of the cleaning procedures will be at the shipper's discretion. We expect that these will be in accord with existing industry best practices. [Comment/Response #125](#) discusses that inspection of vehicle/equipment may be accomplished by any appropriate means, including visual inspection or checking for a wash ticket. The ST rule does not specify any specific measures to determine the sanitary condition of a vehicle/equipment, and has no prescribed criteria to determine the effectiveness of a method. There is no FDA certification or training available at this time pertaining to cleaning trailers.

Under the ST Rule, the shipper would give the carrier information regarding sanitary specifications and cleaning procedures for a vehicle and transportation equipment, per [Sec. 1.908\(b\)\(1\)](#). The shipper must either (1) take measures in accordance with [Sec. 1.908 \(b\)\(3\)](#) to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, or (2) specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. The [shipper's specifications](#) must ensure that the vehicle is in appropriate sanitary condition for the transportation of food in order to prevent the food from becoming unsafe during the transportation operation. The information submitted by the shipper is subject to the records requirement in [1.912\(a\)](#) of the rule. Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, the loader must determine, considering, as appropriate, specifications provided by the shipper, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is 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. This may be accomplished by any appropriate means. The shipper is responsible for communicating to the carrier, or a third-party service provider, the sanitary specifications and cleaning procedures for a vehicle, under Section [1.908\(b\)\(1\)](#) of the ST rule.

The shipper may establish a written agreement with the carrier or another party covered by the rule, to implement written procedures specifying how it will ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. Please see [Comment/Response #16](#) regarding contractual reassignment of responsibilities under the rule. Please note that if a task under the rule is assigned via contract to a party who is not covered by the rule, FDA would hold the party covered by the rule ultimately responsible for compliance with the provisions of the rule. These written agreements would be subject to [record requirements under 1.912](#).

## **SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD 2017**

### ***COMPLIANCE***

#### **ST2017.1 Who must comply with the Rule?**

Generally, the requirements of the Sanitary Transportation rule apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. (21 CFR 1.900(a))

### **Definitions**

The Sanitary Transportation rule uses a number of terms in very specific ways. A full list of these terms appears in this guide in section IX. The terms defined here and in the section “Who is exempt from the requirements of the Sanitary Transportation rule?” will help you determine if your business is subject to the rule. (21 CFR 1.904)

**Table 1--Key Terms Used in Part 1, Subpart O**

<b>Term</b>	<b>Definition</b>
Carrier	A person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Loader	A person that loads food onto a motor or rail vehicle during transportation operations.
Non-covered business	A shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. The baseline year for calculating the adjustment for inflation is 2011.
Receiver	Any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.
Shipper	A person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.
Small business	<ol style="list-style-type: none"> <li>1. A business that is not a motor vehicle carrier and that employs fewer than 500 full-time equivalent employees, or</li> <li>2. A motor vehicle carrier that is not a shipper or receiver that has less than \$27,500,000 in annual receipts.</li> </ol>
Transportation	Any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

## ***EXEMPTIONS***

### **ST2017.2 Who is exempt from the requirements for the Sanitary Transportation Rule?**

Non-covered businesses (see definition in Table 1) are not subject to the rule and therefore do not need to comply with the rule. In addition, shippers, receivers, loaders, or carriers subject to the Sanitary Transportation rule do not need to comply with the rule when they are engaged in the following transportation operations and activities.

See Table 2--Exemptions for Part 1, Subpart O below.

**Table 2--Exemptions for Part 1, Subpart O**

<b>Exemption</b>	<b>Conditions</b>
Transportation operations of food that is transshipped through the U.S. to another country  21 CFR 1.900(b)(1)	
Transportation operations of food that is imported for future export  21 CFR 1.900(b)(2)	
Transportation operations of food located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act  21 CFR 1.900(b)(3)	
Transportation activities performed by a farm  21 CFR 1.904 "Transportation operations"	
Transportation of compressed food gases  21 CFR 1.904 "Transportation operations"	
Transportation of food contact substances  21 CFR 1.904	Food contact substances as defined in section 409(h) of the Federal Food, Drug, and Cosmetic Act
Transportation of human food byproducts for use as animal food without further processing  21 CFR 1.904 "Transportation operations"	See definition of "Transportation operations"
Transportation of food that is completely enclosed by a container  21 CFR 1.904 "Transportation operations"	Except a food that requires temperature control for safety
Transportation of live food animals  21 CFR 1.904 "Transportation operations"	Except molluscan shellfish

## **WAIVER INFORMATION**

### **ST2017.3 Has FDA issued any waivers?**

Yes, FDA has waived the requirements of the Sanitary Transportation rule for three classes of businesses (see Section VIII for additional information about waivers):

1. Businesses holding valid permits that are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program, only when transporting bulk and finished Grade "A" milk and milk products.
2. Businesses authorized by the regulatory authority to operate a food establishment (e.g., restaurants, grocery stores) when engaged in transportation as receivers, or as shippers and carriers in operations in which food is delivered directly to consumers, or to other locations the establishments or affiliates operate that serve or sell food directly to consumers. (This waiver applies to establishments that provide food for human consumption such as restaurants, supermarkets and home grocery delivery services. Establishments that only sell animal food are not included under this waiver. For additional information refer to the "Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule" guidance at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/UCM571341.pdf>).
3. Businesses that are certified and inspected under the requirements established by the Interstate Shellfish Sanitation Conference's (ISSC) National Shellfish Sanitation Program (NSSP) when transporting shellfish (such as oysters, clams, mussels or scallops) in vehicles permitted under ISSC authority.

## **MODIFIED REQUIREMENTS FOR SMALL BUSINESSES**

### **ST2017. 4 Do I have any modified requirements if I am a small business?**

No, all of the requirements of the Sanitary Transportation rule apply to a small business. However a small business has an additional year before it is required to comply with the rule (see Section III). (Also, a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000 in average annual revenues is not covered by the rule. See section II.B.)

## **COMPLIANCE DATES**

### **ST2017.5 When Do I have to Comply with the Rule?**

We encourage you to comply with the Sanitary Transportation rule as soon as possible. However, we are not requiring you to comply with the rule right away. As shown in the table below, the amount of time we are allowing you to comply with the Sanitary Transportation rule depends on the size of your particular business.

Table 3--Compliance Dates for the Sanitary Transportation Rule Based on Size of Business

<b>Size of Business</b>	<b>Compliance Date</b>
Small businesses, i.e., a business other than a motor vehicle carrier with fewer than 500 full-time equivalent employees, or a motor vehicle carrier that is not also a shipper or a receiver that has less than \$27,500,000 in annual receipts	April 6, 2018
Other businesses that do not qualify for exemptions	April 6, 2017

## **VEHICLE AND TRANSPORTATION EQUIPMENT REQUIREMENTS**

### **ST2017.6 What is a vehicle?**

A “vehicle” is a land conveyance that is motorized, such as a motor vehicle, or that moves on rails, such as a railcar, which is used in food transportation operations. (21 CFR 1.904)

## **TEMPERATURE CONTROL FOR SAFETY (TCFS) DURING TRANSPORTATION**

### **ST2017.7 What can be considered transportation equipment?**

“Transportation equipment” means equipment used in food transportation operations and includes items such as bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor. (21 CFR 1.904)

#### **ST2017.8 What requirements apply to vehicles and transportation equipment?**

Vehicles and transportation equipment used in transportation operations must:

- Be designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe during transportation; (21 CFR 1.906(a))
- Be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation; and (21 CFR 1.906(b))
- Be stored in a manner that prevents their harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming unsafe during transportation. (21 CFR 1.906(d))

#### **2T2017.9 Are there specific requirements for vehicles and transportation equipment for food requiring temperature control for safety?**

Yes, vehicles and transportation equipment used in the transportation of food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation. (21 CFR 1.908(c))

### ***SHIPPER, CARRIER REQUIREMENTS AND RESPONSIBILITIES UNDER SFTA***

#### **ST2017.10 If I am both a shipper and a carrier, what requirements am I subject to?**

You must meet the requirements for each function you perform that is subject to the rule, i.e., as a shipper, receiver, loader or carrier. Therefore, if you are functioning as both the shipper and the carrier, you must meet both the shipper’s and the carrier’s requirements. (21 CFR 1.908(a)(1))

If you perform multiple functions under the rule, and are under the ownership or operational control of a single legal entity, as an alternative to meeting the rule’s specific

requirements for shippers, receivers and carriers, you may operate under common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of the Sanitary Transportation rule. Establishing these common integrated procedures may make it easier for you to comply with the rule's requirements. These written procedures are subject to the records requirements of the rule which are discussed in Section VII. (21 CFR 1.908(a)(5))

**ST2017.11 Can I reassign my responsibilities under the rule to another person?**

Yes you can, if the other person is also subject to the rule. For example, if you are a loader, under the rule you would be responsible for verifying that a truck has been pre-cooled as specified by the shipper prior to loading food that requires temperature control for safety. However, you may establish an agreement with the carrier to perform this verification check for you. The carrier will then have this responsibility under the rule. Your agreement with the carrier is subject to the records requirements of the rule discussed in Section VII. (21 CFR 1.908(a)(1)).

**ST2017.12 Who in my company is responsible for making sure that we are following the requirements of this rule?**

Supervisory level personnel in your company must be assigned the responsibility for making sure that your company is meeting the requirements of the Sanitary Transportation rule. (21 CFR 1.908(a)(2))

**ST2017.13 Are there requirements for transportation operations that everyone subject to the rule must meet, in addition to the specific requirements that only apply to specific persons, such as shippers or carriers?**

Yes. Everyone subject to the rule must do these things in their transportation operations:

- You must take effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load. (21 CFR 1.908(a)(3)(i))
- You must take effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. (21 CFR 1.908(a)(3)(ii))
- You must take effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control. (21 CFR 1.908(a)(3)(iii))

## ***ANIMAL FOOD REQUIREMENTS***

**ST2017. 14 Are the requirements of the rule the same for the transportation of human and animal food?**

Yes they are the same inasmuch as they require that food, whether human or animal food, be transported in a manner in which it will not become unsafe during transportation. However, we recognize that in certain instances, different practices to effectively accomplish this purpose have been established for the transportation of human and animal food. For example, certain types of equipment used for the transportation of human food and pet food use stainless steel food contact surfaces, while comparable equipment used for the transportation of animal feed uses a suitable non-stainless grade of steel called mild steel. (21 CFR 1.908(a)(4))

## ***MAINTAINING TEMPERATURE CONTROL DURING TRANSPORTATION***

**ST2017.15 What am I required to do if I notice that food that requires temperature control has been transported in a way in which it could become unsafe, such as in very hot weather on a truck without a refrigeration unit?**

If a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, you must not sell or distribute the food and you must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. (21 CFR 1.908(a)(6))

Therefore, if you are a receiver and your standard procedure is to reject a delivery if it shows an indication of severe temperature abuse or another serious problem, you must also take additional action such as calling the shipper or carrier and informing them of what you observed that may indicate that the food has become unsafe. It then becomes that person's responsibility to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

## ***SHIPPER RESPONSIBILITIES***

### **ST2017.16 As a shipper, what are my responsibilities under this rule?**

As a shipper, you must establish written procedures subject to the records requirements discussed in Section VII, that describe how you conduct your operations to ensure that food does not become unsafe during transportation. There are as many as 3 specific types of written procedures you must establish, depending upon the type of food you ship:

- In all cases, as a shipper, you must develop and implement written procedures adequate to ensure that vehicles and equipment used in your transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., they will prevent the food from becoming unsafe during the transportation operation. You may perform the measures to implement these procedures yourself, or they may be accomplished by the carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(3))
- If you ship food in bulk, you must also develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. You may perform the measures to implement these procedures yourself, or they may be accomplished by the carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(4))
- If you ship food that requires temperature control for safety under the conditions of shipment you must also develop and implement written procedures to ensure that the food is transported under adequate temperature control. You may perform the measures to implement these procedures yourself, or they may be accomplished by the carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. These measures must include measures equivalent to those specified for carriers under 21 CFR 1.908(e)(1), (2) and (3) discussed in Section V. E. (21 CFR 1.908(b)(2))

## ***WRITTEN AGREEMENTS BETWEEN CARRIER AND SHIPPER***

### **ST2017.17 If I establish an agreement with my carrier to implement some of my written procedures, what are my responsibilities with respect to working with my carrier?**

Depending upon the type of food you ship, you would have one or both of the following responsibilities:

- Unless you take other measures as allowed by 21 CFR 1.908(b)(3) to ensure that vehicles and equipment used in your transportation operations are in

appropriate sanitary condition for the transportation of the food, you must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. A 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 you must notify the carrier in writing before the shipment. (21 CFR 1.908(b)(1))

- In addition, if you ship food that requires temperature control for safety under the conditions of shipment, unless you take other measures as allowed by 21 CFR 1.908(b)(5) to ensure that adequate temperature control is provided during transportation of the food, you must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. A one-time notification is sufficient unless a factor, e.g., the conditions of shipment, changes, necessitating a change in the operating temperature, in which case you must so notify the carrier in writing before the shipment. The information you submit to the carrier is subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(2))

## ***LOADER RESPONSIBILITIES***

### **ST2018.18 As a loader, what are my responsibilities under the rule?**

- Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, you must determine, considering, as appropriate, any specifications provided by the shipper, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, for example, it is 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. You may accomplish this by any appropriate means. (21 CFR 1.908(c)(1))
- Before loading food that requires temperature control for safety, you must verify, considering, as appropriate, specifications provided by the shipper, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation. (21 CFR 1.908(c)(2))

## ***RECEIVER RESPONSIBILITIES***

### **ST2018.19 As a receiver, what are my responsibilities under the rule?**

Upon receipt of food that requires temperature control for safety under the conditions of shipment, you must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors. (21 CFR 1.908(d))

## ***CARRIER RESPONSIBILITIES***

### **ST2017.20 Do the requirements of the rule always apply to carriers who transport food?**

The general requirements of the rule apply to all persons subject to the rule, i.e., shippers, receivers, loaders and carriers, at all times when they are engaged in the transportation of food.

However, the specific requirements for carriers in 21 CFR 1.908(e) only apply to the carrier when the carrier and shipper have established a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation. (21 CFR 1.908(e))

### **ST2017.21 What are the specific requirements for carriers when a shipper-carrier agreement has been established?**

When a shipper-carrier agreement has been established, the carrier is responsible for the following functions as applicable under the agreement:

- 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. (21 CFR 1.908(e)(1))
- The carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper, as discussed in Section V. B. 2, and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature. The demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment. (21 CFR 1.908(e)(2))
- 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 under the conditions of the shipment during transportation, the

carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper, as discussed in Section V. B. 2. (21 CFR 1.908(e)(3))

- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle. (21 CFR 1.908(e)(4))
- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle. (21 CFR 1.908(e)(5))
- A carrier must develop and implement written procedures subject to the records requirements discussed in Section VII 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 condition as required by 21 CFR 1.906(b);
  - Describe how it will comply with the provisions for temperature control in 21 CFR 1.908(e)(2), and;
  - Describe how it will comply with the provisions for the use of bulk vehicles in 21 CFR 1.908(e)(4) and (5). (21 CFR 1.908(e)(6))

## ***TRAINING FOR CARRIERS***

### **ST2017.22 What training requirements apply to carriers?**

If you are a carrier and you have a contract with the shipper to be responsible for any sanitary conditions during transportation, you must provide adequate training for your personnel involved in food transportation operations. The training must provide an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under the rule. (21 CFR 1.910(a))

### **ST2017.23 When must training be provided?**

You must provide the training when you hire personnel for food transportation operations and as necessary thereafter. For example, you may need to provide additional training if you previously transported only fully packaged refrigerated items but you now begin transporting produce in open containers and begin using different cleaning procedures for your trucks. (21 CFR 1.910(a))

### **ST2017.24 Do I have to keep records of the training?**

Yes, you must establish and maintain records documenting the training. The requirements for these records are described in the table in Section VII A. (21 CFR 1.910(b))

#### **ST2017.25 Where can I get training for this rule?**

To assist carriers in their efforts to provide training to personnel, FDA offers a free web-based training module that covers the required training elements described above. You may offer this module to your personnel as a means of satisfying the rule's training requirement. The training module is available at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/training-carriers-covered-sanitary-transportation-human-and-animal-food-rule>.

The FDA training module touches on a wide range of transportation food safety topics in a non-detailed manner. We anticipate that some carriers will wish to provide additional training that focuses on company-specific operations and procedures related to food safety.

You are not required to use the FDA training module. You may use training offered by third parties training vendors or you may train your personnel yourself. We do not require training offered by a company or a third party to be approved by FDA or that the instructors be certified.

### ***REQUIRED RECORDS***

#### **ST2017.26 What records am I required to make and keep?**

You are required to make and keep the records shown in Table 4. (21 CFR 1.912)

**Table 4--Records Required Under 21 CFR Part 1, subpart O**

<b>Required Records</b>	<b>Description</b>
Information provided by shippers to carriers  (21 CFR 1.912(a)(1))	Shipper records must demonstrate that the shipper:  Provided, as a regular part of transportation operations, specifications and operating temperatures to carriers as required by 21 CFR 1.908(b)(1)
Written agreements and the written procedures of a shipper  (21 CFR 1.912(a)(2))	The shipper's written agreements and written procedures must meet the requirements of 21 CFR 1.908(b)(3), (4), and (5).

<b>Required Records</b>	<b>Description</b>
Written procedures of a carrier (21 CFR 1.912(b))	The carrier's written procedures must meet the requirements of 21 CFR 1.908(e)(6)
Any written agreements subject to the rule that are not otherwise noted (21 CFR 1.912(d))	Written agreements that assign tasks required by the rule to another person
Records documenting required training by carriers (21 CFR 1.912(c))	The training records must:  (1) Include the date of training, the type of training, and the persons trained; and  (2) Be established and maintained in accordance with other records requirements.  (21 CFR 1.910(b))
Written procedures of firms that operate in more than one capacity under the rule, under the ownership or operational control of a single legal entity, for example, as a shipper and a carrier.  (21 CFR 1.912(e))  This requirement is an alternative to meeting the requirements of 21 CFR 1.908 (b), (d) and (e)	The written procedures must:  Be common integrated procedures that ensure the sanitary transportation of food consistent with the requirements of the rule.  (21 FR 1.908(a)(5))

### **ST2017.27 What are the requirements for my records?**

Your records must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. (21 CFR 1.912(g))

### **ST2017.28 Do my records have to be in electronic format?**

Your records do not have to be in electronic format.

Records that are established or maintained for the Sanitary Transportation rule that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the

requirements of 21 CFR Part 11. However, records that satisfy the requirements of this rule, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. (21 CFR 1.912(h))

### **ST2017.29 How long must I retain my records?**

All persons subject to this rule must retain records of written procedures and written agreements (except as described in the next paragraph) for a period of 12 months beyond when the procedures or agreements are in use in your transportation operations. (21 CFR 1.912(a)(2), (b) and (e))

All persons subject to this rule must retain records of written agreements that assign tasks required by this rule to another person for a period of 12 months beyond the termination of the agreements. (21 CFR 1.912(d))

Shippers must retain records that demonstrate that they provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers. (21 CFR 1.912(a)(1))

Carriers must retain training records required by 21 CFR 1.910(b) for a period of 12 months beyond when the person identified in the record stops performing the duties for which the training was provided. (21 CFR 1.912(d))

### **ST2017.30 Can I store my records offsite?**

Yes, you can store your records offsite, except for records of a carrier's written procedures required by 21 CFR 1.908(e)(6)(i) that describe practices for cleaning, sanitizing and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food. These carrier written procedures must remain onsite as long as the procedures are in use in your transportation operations. (21 CFR 1.912(i))

However any records stored offsite must be able to be retrieved and you must provide the records to us onsite within 24 hours of request for official review. (21 CFR 1.912(ii))

Your electronic records are considered to be onsite if they are accessible from an onsite location. (21 CFR 1.912(i))

### **ST2017.31 Do I have to make my records available to FDA officials?**

Yes, you must make all records required by the Sanitary Transportation rule available to FDA promptly upon oral or written request. (21 CFR 1.912(f))

**ST2017.32 If FDA collects or copies my records are they protected from public disclosure?**

Records collected or copied by FDA will be protected from public disclosure to the extent allowable under 21 CFR Part 20 and under applicable Freedom of Information Act exemptions. (21 CFR 1.912(j))

**WAIVERS**

**ST2017.33 What is a waiver?**

A waiver is a notice published in the Federal Register by which FDA grants that all or some of the requirements of the Sanitary Transportation rule will not be applied to persons, vehicles, food, or nonfood products identified in the notice. A waiver is effective on the date the notice is published. (21 CFR 1.930)

**ST2017.34 How does FDA issue a waiver?**

We will issue a waiver by publishing a notification of the waiver in the Federal Register, when we determine that:

- (a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and
- (b) The waiver will not be contrary to the public interest.

(21 CFR 1.914)

**ST2017.25 When will FDA consider issuing a waiver?**

We will consider whether to waive a requirement of the Sanitary Transportation rule on our own initiative or in response to a petition submitted under 21 CFR 10.30. (21 CFR 1.916 – 1.926)

**ST2017.26 Can FDA modify or revoke a waiver it has issued?**

Yes, we will modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest. (21 CFR 1.932)

If we modify or revoke a waiver, we will follow the procedures set forth in the Sanitary Transportation rule to inform the person who requested the waiver of our determination and to seek public input through the publication of a notice in the Federal Register. We will also publish a notice of our decision and the effective date in the Federal Register. (21 CFR 1.934)

#### **ST2017.27 Has FDA issued any waivers?**

Yes, see Section II C.

### ***DEFINITIONS***

Below is the full list of definitions in the rule (21 CFR 1.904):

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

*Animal food* means food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

*Bulk vehicle* means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

*Carrier* means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term “carrier” does not include any person who transports food while operating as a parcel delivery service.

*Cross-contact* means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

*Farm* has the meaning given in 21 CFR 1.227.

*Food not completely enclosed by a container* means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle.

*Full-time equivalent employee* is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total

number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Loader* means a person that loads food onto a motor or rail vehicle during transportation operations.

*Non-covered business* means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

*Operating temperature* means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, e.g., seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of 21 CFR 1.908(a)(3).

*Pest* means any objectionable animals or insects including birds, rodents, flies, and larvae.

*Receiver* means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

*Shipper* means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

*Small business* means a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to 21 CFR 1.900(a) having less than \$27,500,000 in annual receipts.

*Transportation* means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

*Transportation equipment* means equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets,

loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

*Transportation operations* means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

*Vehicle* means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.

## ENFORCEMENT

### **E1: What are possible consequences for a firm that does not comply with the preventive controls or produce safety regulations?**

It is a prohibited act to fail to meet the requirements of section 418 of the FD&C Act, related to preventive controls, and to fail to comply with the requirements under section 419, related to produce safety (see sections 301(uu) and (vv)). Depending on the nature of the violation, and whether the food is adulterated or misbranded, FDA may consider different regulatory actions. These include:

- the issuance of advisory letters;
- court actions, such as seizure or injunction; and
- administrative actions, such as administrative detention to gain control of adulterated or misbranded products, mandatory recall of violative food, or suspension of a facility's food registration to prevent the shipment of food.

For imported food products, FDA may detain and refuse violative entries, or place imported food products on import alerts to inform FDA field staff that they may detain

(i.e., initiate a refusal of admission) future shipments of a food without physical examination.

## **INTENTIONAL ADULTERATION**

### ***FOOD DEFENSE PLAN***

#### **IA.1 Is the Food Defense Plan Builder an appropriate tool to use to develop my Food Defense Plan?**

FDA released the new [Food Defense Plan Builder \(FDPB\) version 2.0](#). This software program was updated so that the content aligns with the requirements of the IA rule. The FDPB may assist the food industry in meeting many of the requirements of the rule. The FDPB guides users through a series of sections that, when completed, make up the content for a facility's food defense plan. Although the content of the FDPB is consistent with the FDA's existing regulations and guidance, use of the FDPB is voluntary, and using the tool does not guarantee compliance with the rule's requirements or FDA approval of a food defense plan.

To receive email notifications on when updated food defense guidance, tools, and resources are available, you can subscribe to the [FDA food defense email listserv](#), enter your email address, and click on the "Subscribe" tab at the bottom of the webpage.

### ***COMPLIANCE DATES***

#### **IA.2 What are the compliance dates for the Intentional Adulteration Rule?**

The Mitigation Strategies To Protect Food Against Intentional Adulteration rule ([21 CFR Part 121](#); 81 Fed. Reg. 34166) (IA Rule) applies to the owner, operator or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 USC 350d) unless subject to an exemption (see [21 CFR 121.5](#)). Compliance dates for the IA rule are staggered by business size (see table).

Compliance Dates for the IA Rule:

<b>Business Size</b>	<b>Compliance date</b>
Very small businesses	July 26, 2021
Small business	July 27, 2020
All other businesses	July 26, 2019

## ***SMALL BUSINESS DEFINITION***

**IA.3 What is the definition of a very small business? If I am a very small business, what do I have to do and when do I have to comply?**

A [very small business](#) is a business (including any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). Very small businesses are exempt from the full requirements of the rule, but starting on July 26, 2021, they must upon request, provide for official review documentation sufficient to show that the company is a very small business.

There is no attestation form for facilities that are not subject to the IA rule or that may be exempt.

Please see Appendix 3 of the IA draft guidance "[Determination of Status as a Very Small Businesses or Small Businesses Under Part 121: Mitigation Strategies to Protect Food Against Intentional Adulteration](#)" for details on how to calculate whether you are a very small business.

## ***EXEMPTION***

**IA.4 If I am exempted from some requirements of the Preventive Controls for Human Food rule under §117.5(b) (seafood), §117.5(c) (juice), §117.5(d) (LACF), §117.5(e) (dietary supplements), am I also exempted from the Intentional Adulteration rule? Do I need to develop a food defense plan?**

The Mitigation Strategies To Protect Food Against Intentional Adulteration rule ([21 CFR Part 121](#); 81 Fed. Reg. 34166) (IA Rule) rule does not include exemptions for seafood, juice, LACF, or dietary supplements. The IA rule (21 CFR Part 121; 81 Fed. Reg. 34166) applies to the owner, operator or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 USC 350d) unless subject to an exemption (see [21 CFR 121.5](#)). The rule requires covered facilities to prepare, or have prepared, and implement a written food defense plan that includes a written

- (1) vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps;
- (2) mitigation strategies including required explanations;

- (3) procedures for the food defense monitoring of the implementation of the mitigation strategies;
- (4) procedures for food defense corrective actions; and
- (5) procedures for food defense verification (see [21 CFR 121.126](#)).

## **REGISTRATION**

**REG1: If my farm is registered with FDA but I am not required to register it, how do I cancel the registration, or will FDA cancel the registration?**

Cancellations of registrations must follow the requirements in 21 CFR 1.235. For example, cancellations must include the required information (e.g., registration number, facility name and address) (see 21 CFR 1.235(b)). In addition, as specified in 21 CFR 1.241(c), we will cancel registrations if we independently verify that a facility is not required to register.

## **PRODUCE SAFETY RULE**

### ***SUBPART A – GENERAL PROVISIONS***

**PSR.1 What are the key requirements and compliance dates?**

More information about the final rule can be found on the [FSMA Final Rule on Produce Safety](#) webpage.

**PSR.2 Is extra time allowed for smaller farms to come into compliance with the requirements?**

The FDA has staggered the compliance dates, based on the size of farms, to provide additional time for small and very small farms to come into compliance with the requirements. Additionally, FDA has issued a final rule extending, for covered produce other than sprouts, the dates for compliance with the agricultural water requirements in Subpart E. Because they present special safety concerns, operations growing sprouts have less time to come into compliance than other farms and do not get additional time to come into compliance with any of the water requirements. Farms with an average annual value of produce sold of \$25,000 or less (adjusted for inflation) during the previous three-year period are not covered by the rule.

***PRODUCE: COVERED AND NOT COVERED***

### PSR.3 What produce is covered by this rule, and what produce is not covered?

The rule covers produce as that term is defined in [21 CFR 112.3](#). However, certain produce is excluded from the rule. Specifically, the rule does not cover produce that:

- is grown for personal or on-farm consumption
- is not a “raw agricultural commodity.” (A raw agricultural commodity is any food in its raw or natural state. See [Section 201\(r\) of the Federal Food, Drug, and Cosmetic Act](#) (FD&C Act).
- is identified as “rarely consumed raw”. The “rarely consumed raw” list at [21 CFR 112.2\(a\)\(1\)](#) is exhaustive and contains the following fruits and vegetables: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.

In addition, produce that will receive commercial processing that adequately reduces microorganisms of public health concern (i.e., a “kill step”) is eligible for exemption from the rest of the rule if certain requirements are followed, including making a disclosure statement and keeping certain documentation.

### COVERED FARMS

#### PSR.4 Is my farm covered by the Produce Safety Rule?

The Produce Safety Rule does not cover farms that have an average annual value of **produce** sold during the previous 3-year period of \$25,000 or less, adjusted for inflation. To determine whether a farm is potentially a covered farm with respect to the \$25,000 threshold in [21 CFR 112.4\(a\)](#), the farm would need to calculate the average annual monetary value of their produce sales during the previous three years. Available resources include: the [flowchart](#) to determine if the farm may be subject to the Produce Safety Rule; and the webpage, “[FSMA Inflation Adjusted Cut Offs](#).”

### QUALIFIED EXEMPTION

#### PSR.5 Is my farm eligible for a qualified exemption from the Produce Safety Rule?

If a farm’s average annual produce sales exceed \$25,000, the farm may still be eligible for a qualified exemption and modified requirements if it meets two requirements: (1) The farm must have **food** sales averaging less than \$500,000 (adjusted for inflation) per

year during the previous 3 years; and (2) during that time, the farm's sales directly to qualified end-users must have exceeded sales to others (see [21 CFR 112.5](#)). A qualified end-user is either: (1) The consumer of the food or (2) a restaurant or retail food establishment (as those terms are defined in [21 CFR 1.227](#)) that is located in the same State or the same Indian reservation as the farm or not more than 275 miles from the farm (see [21 CFR 112.3](#)). Read more about the [current dollar value for food sales adjusted for inflation related to a qualified exemption](#).

## QUALIFIED END-USER

### PSR.6 What is a qualified end-user?

A qualified end-user, with respect to a food, means either the consumer of the food (does not include a business); or a restaurant or retail food establishment (as defined in [21 CFR 1.227](#)) that is located:

- (1) In the same State or the same Indian reservation as the farm that produced the food; or
- (2) Not more than 275 miles from such farm.

According to 21 CFR 1.227, **restaurant** means a facility that prepares and sells food directly to consumers for immediate consumption and 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.

- (1) Entities in which food is provided to humans, 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; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

A **retail food establishment** is an establishment that sells food products directly to consumers as its primary function, i.e., the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers (see full definition at [21 CFR 1.227](#)). Grocery stores and convenience stores are examples of retail food establishments. The definition of retail food establishment was recently revised in the final rule, *Amendments to Registration of Food Facilities* ([81 FR 45912, July 14, 2016](#)), to provide certain clarifications about what types of sales may be considered sales directly to consumers for purposes of this definition.

More information about the terms “restaurant” and “retail food establishment” can be found in FDA’s guidance document titled [Questions and Answers Regarding Food Facility Registration \(Seventh Edition\): Guidance for Industry](#).

## ***SUBPART C – PERSONNEL QUALIFICATIONS AND TRAINING***

### ***TRAINING OF PERSONNEL***

#### **PSR.7 Which personnel must be trained?**

All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person’s duties, upon hiring, and periodically thereafter, at least once annually. See [21 CFR 112.21\(a\)](#).

#### **PSR.8 How frequently do my personnel need to be trained?**

Upon hiring, and periodically thereafter, at least once annually. Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in the Produce Safety Rule Subparts C through O ([21 CFR 112.21](#)).

### ***TRAINING RECORDS***

#### **PSR.9 What training records are required by the Produce Safety Rule?**

You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the person(s) trained ([21 CFR 112.30\(b\)](#)).

### ***STANDARDIZED CURRICULUM***

#### **PSR.10 Do we need to obtain a certificate in order to satisfy the Produce Safety Rule training requirement under § 112.22 (c)?**

No. We see the value of receiving a “training certificate” or a “food safety certificate” documenting the training farm personnel (including supervisors or responsible parties) have received. However, at this time, we are not requiring use of such a program (either as a new requirement or to satisfy any of the requirements of this rule), nor are we able to develop such a system or recommend a specific certification process or certification body to enable such an approach. Note that although “certificates” are not required, under 21 CFR 112.30(b) you must establish and keep records of training that document

required training of personnel, including the date of training, topics covered, and the persons(s) trained ([80 FR 74353 at 74418-19, November 27, 2015](#)).

## **CONTRACT HARVESTERS**

### **PSR.11 Who can train contract harvesters?**

Where a covered farm uses contracted harvest personnel to harvest covered produce on the farm's behalf, the farm continues to be required to fulfill all relevant duties applicable under this rule. Thus, the farm is responsible for ensuring that the harvest personnel has received required training. The farm may rely on the company that provides the harvest personnel to provide or conduct the training, or the farm may provide or conduct the training. For example, if the harvest company provides training to workers who move from farm to farm under the employment of the harvest company, farms that employ such harvest personnel may choose to rely on the harvest company to provide or conduct the training, request relevant certification from the harvest company, and maintain appropriate records to demonstrate compliance with the applicable training requirements. In addition, an operation that harvests crops but does not grow them, such as a contract harvest company, may meet the definition of "farm" (see [21 CFR 112.3](#)). Thus, if they are covered farms, contracted harvest companies also have duties to comply with this rule ([80 FR 74353 at 74420](#)).

## **SUBPART D – HEALTH AND HYGIENE**

### **MEASURES TO PREVENT ILL OR INFECTED PERSONS FROM CONTAMINATING COVERED PRODUCE**

#### **PSR.12 What measures are required to prevent ill personnel from contaminating covered produce?**

You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

You must exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health.

You must instruct personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

## *HANDWASHING*

### **PSR.13 When are personnel required to wash their hands?**

When handling covered produce or food contact surfaces during covered activities, personnel must thoroughly wash hands before starting work, before putting on gloves, after using the toilet, upon return to the work station after any break or other absence from the work station, as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin, and at any other times when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards.

## ***SUBPART E – AGRICULTURAL WATER***

### *STATUS OF THE AGRICULTURAL WATER REQUIREMENTS*

#### **PSR.14 Why is FDA considering how best to achieve public health protections in the covered produce agricultural water arena, and what does that process involve?**

Agricultural water can be a major conduit of pathogens that can contaminate produce. The feedback that the FDA has received is that some of the agricultural water standards in the Produce Safety Rule may be too complex to understand, translate, and implement for some covered farms. These factors can be important to achieving high rates of compliance. In response to these concerns, the FDA is now working on a rulemaking to propose an approach that offers flexibility and addresses the practical challenges of implementing some of the agricultural water requirements across the diversity in farm types, water sources, and water uses.

Throughout this process, FDA has engaged with stakeholders to learn more from farmers, state regulatory partners and other stakeholders about the diverse ways water is used to ensure that the agricultural water standards will be as practical and effective as possible for all farming operations. We are assessing not only which aspects of the agricultural water standards are proving most challenging for growers, but also the appropriate mechanism for addressing those concerns.

We aim to be as transparent as possible moving forward, and we remain committed to protecting public health while implementing rules that are workable across the diversity of the food industry.

### *COMPLIANCE WITH CURRENT AGRICULTURAL WATER REQUIREMENTS*

**PSR.15 While FDA is considering how best to achieve public health protections in the covered produce agricultural water arena, are non-sprout farms expected to comply with the current agricultural water requirements?**

No. FDA has issued a final rule extending, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health. See [84 FR 9706](#) (March 18, 2019).

FDA encourages farms to continue to use good agricultural practices to maintain and protect the quality of their water sources. (See, e.g., FDA's "[Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables](#)") Farms currently testing their water may choose to continue with their current water testing programs, and farms that are not currently testing their water may choose to begin doing so.

While this rule extends the compliance dates for the agricultural water provisions, produce remains subject to the other provisions of the Produce Safety Rule (as applicable), and the adulteration provisions of the FD&C Act.

***SUBPART F – BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE***

***DETERMINING BSAAO***

**PSR.16 Does the definition of "biological soil amendment of animal origin" in the Produce Safety Rule include seafood-derived material? In other words, are fish considered animals for the purposes of this rule? Does this include shellfish? Does it include shellfish shells after the actual organism is removed?**

The definition of BSAAO, in [21 CFR 112.3](#), means any soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts. Non-fecal animal byproduct, which is also defined in 21 CFR 112.3, means solid waste (other than manure) that is animal in origin and is generated by commercial, institutional, or agricultural operations. Examples of non-fecal animal byproduct include fish meal, shellfish waste, and fish emulsions.

***HUMAN WASTE***

**PSR.17 Would the provisions of the Produce Safety Rule impact the use of biosolids for the growing of vegetable crops or other covered produce?**

You may not use human waste for growing covered produce, except that sewage sludge biosolids may be used in accordance with EPA regulations in [40 CFR part 503, subpart D](#) (Pathogens and Vector Attraction Reduction), or equivalent regulatory requirements (see [21 CFR 112.53](#)). “Sewage sludge biosolids” are defined in [21 CFR 112.3](#) as the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of “sewage sludge” in 40 CFR 503.9(w).

## *TREATMENT PROCESSES*

**PSR.18 What are some examples of "scientifically valid methods" that may be used to treat raw manure, during the production of stabilized-and-cured compost, so that it can be used in the production of fresh produce as a treated BSAAO?**

We would first like to point to a few definitions in the Produce Safety Rule to help clarify our response.

[21 CFR 112.3](#) defines “composting” as a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131°F (55°C)), followed by a curing stage under cooler conditions.

“Curing” is further defined as the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

[21 CFR §112.54\(b\)](#) provides two examples of scientifically valid controlled biological processes (e.g., composting) that meet the relevant microbial standard. The first is static composting that maintains oxygenated conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing. The second is turned composting that maintains oxygenated conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing. In either case, the resulting biological soil amendment must be applied in accordance with the applicable requirements of [21 CFR 112.56](#). Additionally, for a treated BSAAO you produce for your own covered farm, you must

establish and maintain documentation that process controls (for example, time, temperature, and turnings) were achieved per [21 CFR 112.60\(b\)\(2\)](#).

Note that there may be additional processes in addition to those described in 21 CFR §112.54(b) that satisfy the requirements in 21 CFR §112.54 for treated BSAAOs

#### **MICROBIAL STANDARDS FOR TREATMENT PROCESSES**

#### **PSR.19 What are the set microbial limits for *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7, and do these limits apply to both stabilized compost and raw manure?**

We have provided the microbial standards against which treatment processes must be validated (see [80 FR 74353 at 74472](#) (Comment/Response 288)), and the rule allows for use of controlled physical, chemical, or biological treatment processes, or combinations thereof (including composting) that achieve those microbial standards. The rule does not require microbiological testing of treated BSAAO to ensure that they meet the relevant microbial standards.

For a BSAAO to be considered “treated” for the purposes of 21 CFR 112.51, the BSAAO must be treated via a process described in 21 CFR 112.54 that meets the applicable microbial standards in 21 CFR 112.55.

The following microbial standards apply to the treatment processes in 21 CFR 112.54:

(a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7:

<b>For the microorganism—</b>	<b>The microbial standard is—</b>
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

Or, (b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams (or milliliter, if liquid is being sampled) of total solids; and less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids.

Raw manure must be regarded as “untreated” under 21 CFR 112.51. See [80 FR 74353 at 74472](#) (Comment/Response 277). Stabilized compost may be considered “treated” provided that the compost treatment process has been validated to meet the applicable requirements, including satisfying one of the microbial standards in [21 CFR 112.55](#). Examples of composting that satisfy treatment process requirements in [21 CFR 112.54\(b\)](#) and satisfy the microbial standard in 21 CFR 112.55(b) are found in 21 CFR 112.54(b)(1) and 21 CFR 112.54(b)(2).

#### *APPLICATION REQUIREMENTS AND MINIMUM APPLICATION INTERVALS*

**PSR.20 How does the FDA plan to determine how much time should be required between the application of raw manure and the harvest of produce covered by the rule?**

The final produce rule contains requirements related to the safe use of biological soil amendments of animal origin, including raw manure, in Subpart F. With regard to the application of untreated biological soil amendments of animal origin, including manure, applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, the FDA is deferring action on an application interval until we pursue certain steps, including a risk assessment and research to supplement the science on an appropriate interval. We anticipate that these efforts will take five to 10 years to complete. Following the completion of the risk assessment and research work, we expect to: (1) provide stakeholders with data and information gathered from scientific investigations and risk assessment; (2) consider such new data and information to develop tentative scientific conclusions and regulatory decisions; (3) provide an opportunity for public comment on our tentative decisions; and (4) consider public input to finalize the provision(s) establishing an appropriate minimum application interval(s). See [80 FR 74353 at 74462-63](#) (Comment/Response 257).

#### *RECORDS REQUIREMENTS FOR BSAAO*

**PSR 21. Should bagged grass clippings from lawn care companies be considered BSAAOs due to the possibility of inclusion of domesticated animal feces?**

First, we note that the definitions of “yard trimmings” and “pre-consumer vegetative waste” in 21 CFR 112.3 stipulates that these are purely vegetative materials. To the extent that vegetative waste is known to include animal feces, it would not meet the definitions of “yard trimmings” or “pre-consumer vegetative waste,” and a soil amendment made from such material would instead be a biological soil amendment of animal origin included in the scope of the provisions of subpart F. However, we recognize that even in purely vegetative material such as that described in the definition of “yard trimmings” or “pre-consumer vegetative waste,” there is the potential for unknown and unavoidable contamination with animal waste. We have concluded that the likelihood of contaminating produce with pathogens by use of biological soil amendments that are not known to contain, and not likely to contain significant animal waste or human waste (e.g., yard trimmings, pre-consumer vegetative waste) is low, and therefore they are not subject to the requirements of this rule. See [80 FR 74353 at 74464](#) (Comment/Response 263).

## ***SUBPART I – DOMESTICATED AND WILD ANIMALS***

### ***GRAZING ANIMALS, WORKING ANIMALS, AND ANIMAL INTRUSION***

**PSR.22 If livestock are allowed to graze amongst nut or fruit trees, is it required to remove livestock from the orchard prior to harvest? If so, how many days in advance?**

FDA continues to believe that an adequate waiting period between grazing and harvest is an important consideration when, under the circumstances, there is a reasonable probability that grazing animals will contaminate covered produce. As discussed in the 2013 proposed rule and our Qualitative Assessment of Risk, domesticated animals can be a source of human pathogens. Some human pathogens of public health concern (e.g., *E. coli* O157:H7) that have been associated with produce-related foodborne outbreaks can be transmitted from animals to people. Moreover, domesticated animals, due to their proximity and interaction with humans, are generally more likely to harbor zoonotic pathogens than are wild animals. The likelihood of contaminating produce with human pathogens from excreta from grazing animals is determined by numerous factors, including, but not limited to, the species of the animal and its association with human or domesticated animal activity or waste, the number of animals per unit area of land, agro-ecological conditions, the type of commodity and the time between animal grazing in fields and the harvest of produce.

However, currently available science does not allow us to identify a specific minimum time period between grazing and harvesting that is generally applicable across various

commodities and farming practices. Rather, the appropriate minimum time period between grazing and harvesting would need to be determined based on the specific factors applicable to the conditions and practices associated with growing and harvesting the commodity. However, we encourage covered farms to voluntarily consider applying such waiting periods, as appropriate for the farm's commodities and operations.

Under [21 CFR 112.83](#), we are requiring that you take the same steps if, under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce (21 CFR 112.83(a)). In such cases, you must assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience) (21 CFR 112.83(b)(1)). If you find evidence of potential contamination during that assessment (such as observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of [21 CFR 112.112](#), and you must take measures reasonably necessary during growing to assist you later during harvest when under 21 CFR 112.112 you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (21 CFR 112.83(b)(2)).

Assessing the growing areas as needed during the growing season will enable you to identify instances when covered produce cannot be harvested for safe consumption, such as produce that was directly exposed to animal excreta or that may be cross-contaminated during harvest (e.g., contamination of covered produce by contact with a food-contact surface that contacted animal excreta). Depending on the quantity of animals, extent of animal excreta, or extent of crop destruction, the affected growing areas may be localized (for example, a specific area of the field where you allowed grazing) or more widespread. We expect that, in cases of grazing and working animals, in particular, it is more likely that affected areas will be localized because grazing or working animals are expected to be present intermittently and in known areas of the field. Once you identify produce, or an area of produce, that cannot be harvested in accordance with 21 CFR 112.112, 21 CFR 112.83(b)(2) requires you to take measures reasonably necessary during growing to assist you later during harvest in complying with the requirements of 21 CFR 112.112. For example, if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other

occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time of harvest, such as if a significant rain event washes away fecal deposits.

FDA recognizes the longstanding co-location of animals and plant food production in agriculture. This rule does not prohibit the use of grazing or working animals on covered farms.

## ***SUBPART K- GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES***

### ***GROWING, HARVESTING, PACKING OR HOLDING BOTH COVERED AND EXCLUDED PRODUCE***

#### **PSR.23 What are the requirements for packing potatoes and parsnips using the same packinghouse equipment?**

Parsnip is a covered commodity under the Produce Safety Rule (see [21 CFR 112.1\(b\)\(1\)](#), listing parsnips as an example of covered produce). On the other hand, potatoes are not a covered commodity under the Produce Safety Rule (see [21 CFR 112.2\(a\)\(1\)](#), listing potatoes as rarely consumed raw). However, we do want to emphasize that potato farms, and potatoes, are still subject to all applicable requirements of the FD&C Act even though they are exempt from the Produce Safety Rule.

There are provisions in the Produce Safety Rule that would be relevant to a covered farm that produces both parsnips and potatoes. For example, when using shared equipment to grow, harvest, pack or hold both covered (e.g. parsnips) and excluded produce (e.g. potatoes) it is important for covered farms to consider [21 CFR 112.111](#), which requires that if the excluded produce is not grown, harvested, packed or held in accordance with the Produce Safety Rule, you must take measures as applicable, to:

- (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
- (b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

As another example, Subpart L of Part 112 contains requirements for covered farms

with respect to equipment, tools, buildings, and sanitation. This includes requirements regarding adequacy of equipment, cleaning and sanitizing of equipment, and storage and maintenance of equipment (see especially [21 CFR 112.123](#)).

## ***SUBPART L - EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION***

### ***EQUIPMENT AND TOOLS SUBJECT TO REQUIREMENTS OF THIS SUBPART***

#### **PSR.24 What equipment and tools are subject to the requirements of the PSR?**

As explained in [21 CFR 112.121](#), equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include, knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, equipment used to store or convey harvested produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

### ***DOMESTICATED ANIMALS***

#### **PSR.25 I operate a hydroponic greenhouse that is a fully-enclosed building. Is it permissible to have a dog or cat in the greenhouse?**

The provisions in subpart L of the Produce Safety Rule apply to any fully or partially-enclosed buildings used for covered activities, including greenhouses (see [80 FR 74353 at 74491](#) (Comment/Response 344)). Under Subpart L, domesticated animals in and around a fully-enclosed building are not prohibited, however, you must comply with the requirements of [21 CFR 112.127](#). For more information, see the next question.

#### **PSR.26 What requirements apply regarding domesticated animals in and around a fully-enclosed building?**

You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or

(2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition. (21 CFR 112.127(a))

Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials. (21 CFR 112.127(b))

## ***SUBPART M – SPROUTS***

### **PSR.27 Why does the final rule contain additional requirements for sprout production?**

Sprouts present a special concern with respect to human pathogens compared to other covered produce because of the warm, moist and nutrient-rich conditions in which they grow. They have frequently been associated with outbreaks of foodborne illness. ([See 80 FR 74353 at 74367 \(Comment/Response 19\)](#)). The Produce Safety Rule includes specific requirements in Subpart M for most sprouts, which are in addition to the other applicable provisions of the Produce Safety Rule. Subpart M does not cover sprouts that are soil- or substrate-grown and are harvested without their roots (see 21 CFR 112.141); however, such sprouts are still “covered produce” and, unless exempt or excluded under the provisions of subpart A, are subject to all other applicable requirements of the Produce Safety Rule (see [80 FR 74353 at 74497 \(Comment/Response 364\)](#)).

## ***SUBPART O – RECORDS***

### ***RECORD REQUIREMENTS***

### **PSR.28 What are the Produce Safety Rule requirements regarding records?**

Except as otherwise specified, all required records must include, as applicable:

1. The name and location of your farm (21 CFR 112.161(a)(1)(i));
2. Actual values and observations obtained during monitoring (21 CFR 112.161(a)(1)(ii));
3. An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record (21 CFR 112.161(a)(1)(iii));
4. The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record (21 CFR 112.161(a)(1)(iv)); and

5. The date and time of the activity documented (21 CFR 112.161(a)(1)(v)).

Except as otherwise specified, required records must also:

1. Be created at the time an activity is performed or observed (21 CFR 112.161(a)(2));
2. Be accurate, legible, and indelible (21 CFR 112.161(a)(3)); and
3. Be dated and signed or initialed by the person who performed the activity documented (21 CFR 112.161(a)(4)).

Certain required records must be reviewed, dated, and signed by a supervisor or a responsible party within a reasonable time after the records are created (21 CFR 112.161(b)). These records include, as applicable:

1. Records related to eligibility for the qualified exemption (21 CFR 112.7(b));
2. Records related to required training of personnel (21 CFR 112.30(b));
3. Records documenting the results of all analytical tests conducted on agricultural water for purposes of compliance (21 CFR 112.50(b)(2));
4. Records documenting the results of water treatment monitoring under 21 CFR 112.43(b) (21 CFR 112.50(b)(4));
5. Records documenting actions you take in accordance with 21 CFR 112.45 (21 CFR 112.50(b)(6));
6. Records related to process controls for treating biological soil amendments of animal origin you produce for your own covered farm(s) (21 CFR 112.60(b)(2));
7. Records related to cleaning and sanitizing of equipment (21 CFR 112.140(b)(1) and (2)); and
8. Records documenting your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, records of documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of 21 CFR 112.142(e) (21 CFR 112.150(b)(1));
9. Records documenting the results of all analytical tests conducted for purposes of compliance with Subpart M (21 CFR 112.150(b)(4))
10. Records documenting actions you take in accordance with 21 CFR 112.142(b) and (c), 112.146, and 112.148 (21 CFR 112.150(b)(6)).

## *RECORD REQUIREMENTS IN DETERMINING A QUALIFIED EXEMPTION*

### **PSR.29 What types of records do I need to keep if my farm is eligible for a qualified exemption from the Produce Safety Rule?**

A farm is required to establish and keep adequate records necessary to show that it satisfies the criteria for a qualified exemption that are described in [21 CFR 112.5](#),

including a written record reflecting that an annual review and verification of the farm's continued eligibility for the qualified exemption was performed (see 21 CFR 112.7(b)).

You must establish and keep records required under [21 CFR 112.7](#) in accordance with the requirements of subpart O of this part, except that the requirement in 21 CFR 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under 21 CFR 112.161(a)(4) (see 21 CFR 112.7(a)).

## ***SUBPART P - VARIANCES***

### ***REQUESTING A VARIANCE***

#### **PSR.30 Who may request a variance?**

A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where they determine that (a) The variance is necessary in light of local growing conditions; and (b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements of this part.

### ***PROCESS FOR REQUESTING A VARIANCE***

#### **PSR.31 How may a State, tribe, or foreign country request a variance?**

To request a variance from one or more requirements of the Produce Safety Rule, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition using the petition process in 21 CFR 10.30.

## ***SUBPART Q - COMPLIANCE AND ENFORCEMENT***

### ***AUDITS OR CERTIFICATION***

#### **PSR.32 Is there an audit or certification process required to prove compliance under the FSMA Produce Safety Rule?**

FDA is not establishing requirements in the Produce Safety Rule for audits of covered farms. It is the responsibility of the entities subject to the Produce Safety Rule to ensure that they are in compliance with all of the applicable requirements by the applicable compliance date(s). Farms may opt to have third parties evaluate their operations, such as through a USDA GAPs audit or GFSI certification; however, we are not establishing

requirements in the Produce Safety Rule for audits or certification of covered farms (See [80 FR 74353 at 74507](#) (Comment/Response 384)).

We do intend to pursue the goal of making third-party audits an important part of our compliance strategy by building on current private audit activity and by working with the produce industry and other government and private partners to improve the rigor and reliability of private audits. We believe that strengthening both the quality and credibility of private audits will help improve food safety, especially if conducted on the basis of the standards in this rule, but it can also be the basis for streamlining current audit practices and making them more efficient. We seek public-private collaboration to achieve this goal (see [80 FR 74353 at 74521](#)).

One example of these efforts is the [announcement](#) made by FDA and the USDA in June of 2018 regarding the alignment of the USDA [Harmonized Good Agricultural Practices Audit Program](#) (USDA H-GAP) with the requirements of the FDA Food Safety Modernization Act's (FSMA's) [Produce Safety Rule](#). While the requirements of both programs are not identical, the relevant technical components in the FDA Produce Safety Rule are covered in the USDA H-GAP Audit Program. The aligned components include areas such as biological soil amendments; sprouts; domesticated and wild animals; worker training; health and hygiene; and equipment, tools and buildings. The alignment will help farmers by enabling them to assess their food safety practices as they prepare to comply with the Produce Safety Rule. However, the USDA audits are not a substitute for FDA or state regulatory inspections.

While third party audits are not required under the Produce Safety Rule, we do note that private audits may be relevant to some aspects of compliance with the supplier verification requirements in the FSVP and preventive controls regulations, where a farm supplies produce to an importer or receiving facility that seeks to verify that the farm has adequately controlled applicable hazards (see [80 FR 74353 at 74521](#)). Under the final Accredited Third-Party Certification Rule, FDA established a voluntary program for the accreditation of third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce. These requirements are intended to help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program. See [FSMA Final Rule on Accredited Third-Party Certification](#).