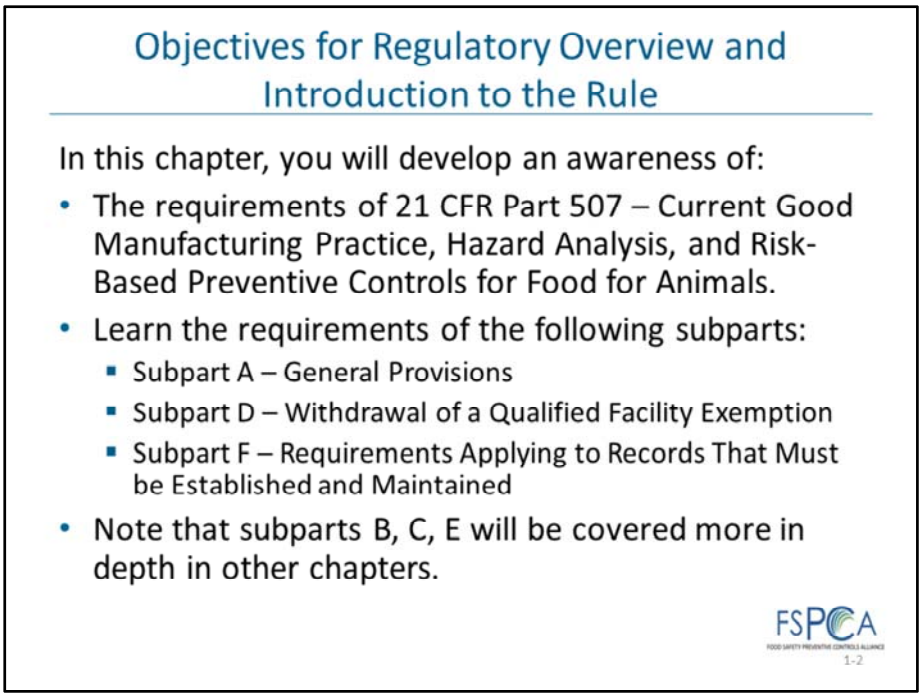
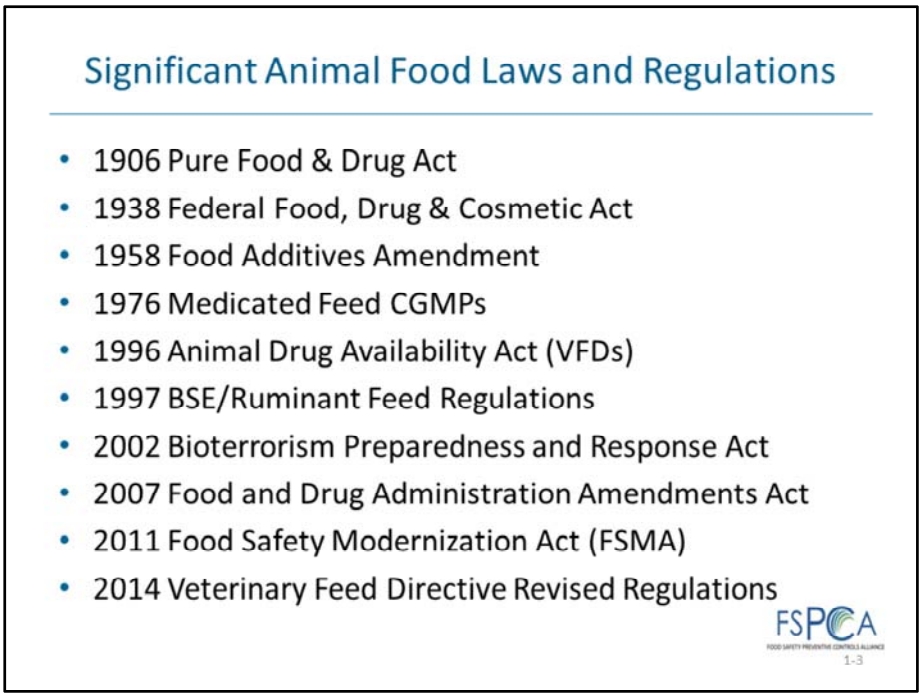
This course is one way to meet the requirements to be a *Preventive Controls Qualified Individual.* The course will help participants distinguish between Current Good Manufacturing Practices (CGMPs), other prerequisite programs, and preventive controls and understand how they fit into the regulatory framework so that hazards are adequately controlled. The course will also help participants understand the hazard analysis process and how to use available resources to conduct a thorough analysis. The course's final outcome is to learn concepts needed to build a food safety plan.

Participants will not walk away from this course with a completed food safety plan for a specific facility. The course will discuss different examples as a way to help participants understand core concepts. This course is to help participants understand how to write and implement the required components of a food safety plan as a part of a larger food safety system, not to write a specific plan. Development of the food safety plan for a specific facility likely needs to be done with consultation of the facility's food safety team and may take weeks to complete.



In this chapter, participants will develop an awareness of the requirements of the *Preventive Controls for Animal Food* rule and learn some background information on FSMA and the Preventive Controls for Animal Food rule and some of the specific requirements of subparts A, D, and F. Note that subparts B, C, and E will be summarized in this chapter, but are covered in more depth in later chapters.

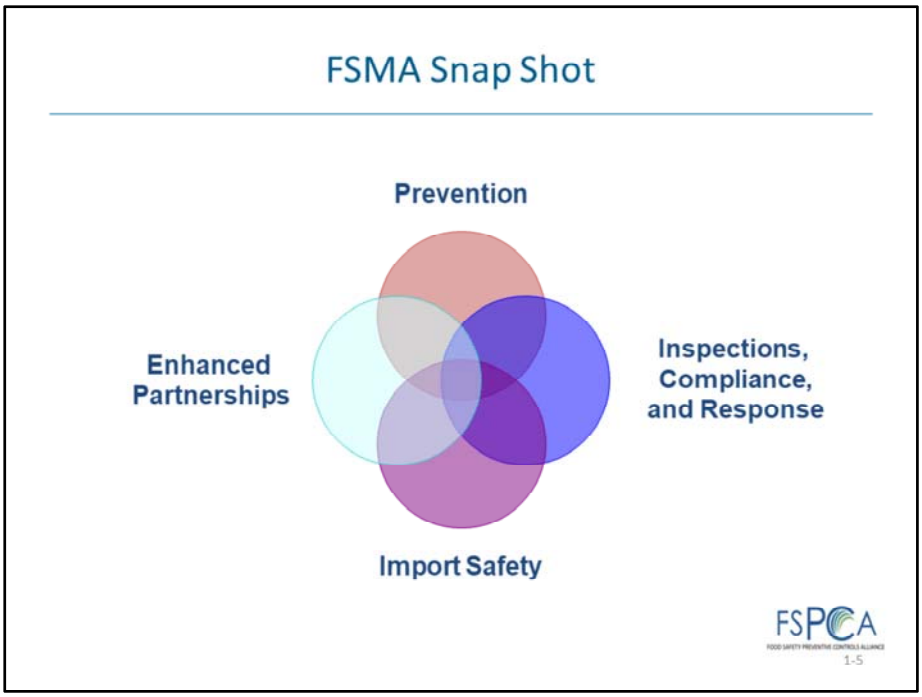


It is sometimes helpful to reflect on other significant laws and regulations enacted that impact animal food safety. Many of these laws and regulations helped form the foundation for animal food safety regulations prior to the *Preventive Controls for Animal Food* rule, while others are tangential to its objective.

The existing laws and regulations for animal food established a framework for regulation of animal food in the United States. From the definitions established in the Federal Food, Drug, and Cosmetic Act to the concepts of Current Good Manufacturing Practices, compliance inspections, recordkeeping, hazard control, and traceability, all of these previously existing laws and regulations set a foundation for the basis of the *Preventive Controls for Animal Food* rule. The *Preventive Controls for Animal Food* rule was developed as directed by Congress in the Food Safety Modernization Act, or FSMA. The *Preventive Controls for Animal Food* rule and the existing laws and regulations will work together to ensure the safety of the U.S. animal food supply.

The Food Safety Modernization Act (FSMA) was signed into law in January 2011. The law was drafted because Congress felt that current food safety had the opportunity for improvement. At the time the law was passed, data from the Centers for Disease Control and Prevention (CDC) reported that 1 in 6 million Americans, about 48 million, were sickened, 128,000 hospitalized, and 3,000 died each year from foodborne diseases. Animal food can cause illness or death of animals, which includes both pet animals and food-producing animals. Given the complex nature of the animal food supply and increasing globalization of the animal food supply, animal food was incorporated into FSMA so that animal food hazards impacting animal and human health were controlled throughout the food supply.

The FDA has described FSMA as the most sweeping reform of our food safety laws in more than 70 years. This is quite the statement considering that several of the laws and regulations described on the previous slide had major impacts on the animal food industry. The goal of the FSMA is to aim to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

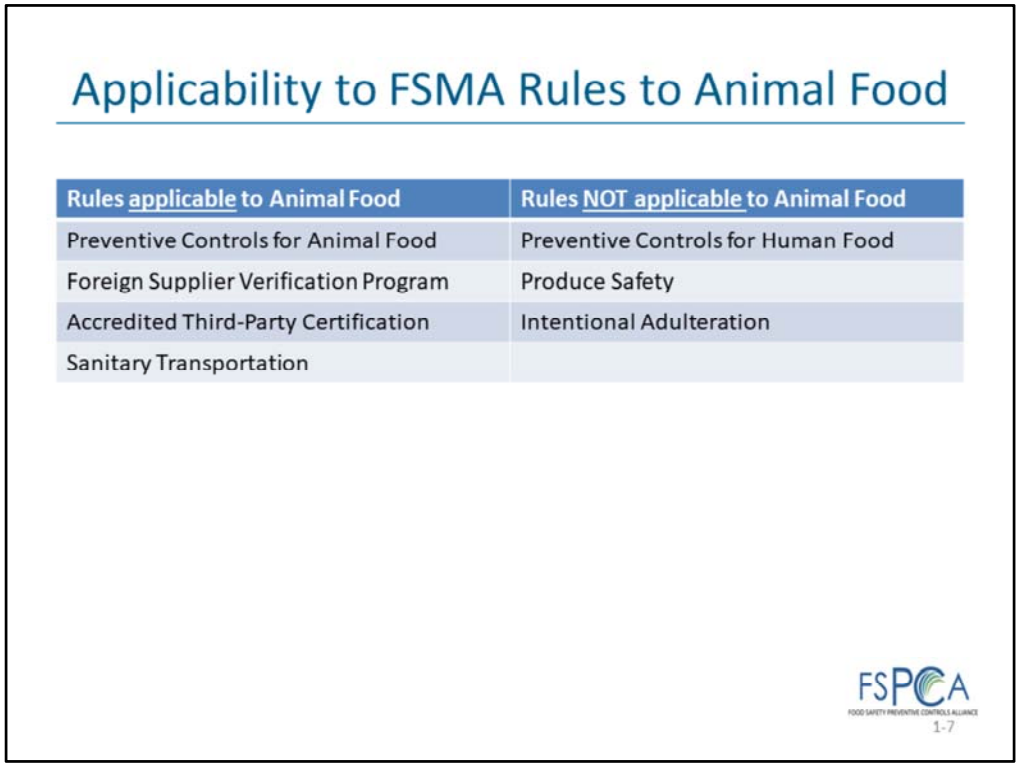


There are four main themes of FSMA: prevention, enhanced partnerships, import safety, and inspections/compliance/ response. These themes mandate FDA to:

1. Enhance partnerships between domestic and foreign government agencies, such as through the creation of the domestic integrated food safety system;
2. Help ensure that imported food meets U.S. food safety standards;
3. Conduct food facility inspections at a required frequency and utilize new tools to ensure compliance and help respond more quickly when food safety problems are detected; and
4. Create a regulatory system that prevents the occurrence of food safety hazards.

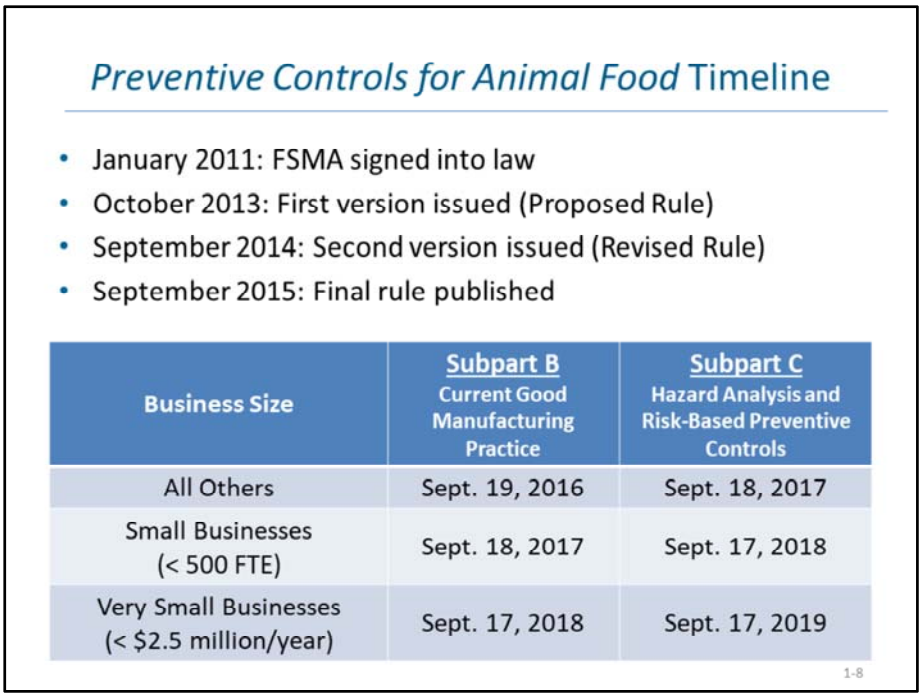
It is Theme 4: Prevention that is the focus of the *Preventive Controls for Animal Food* rule described by this curriculum.

Congress directed FDA to create regulations to fully implement the four themes of FSMA. Because FSMA is so multifaceted, many rules are required for its implementation. The initial rule making has resulted in seven major rules that together form the new foundation for food safety for human and animal food. The seven major final rules were published between September 2015 and May 2016.



Of the seven major final FSMA rules, only 4 of the 7 have application to the animal food industry. The *Preventive Controls for Animal Food*, *Foreign Supplier Verification Program*, *Accredited Third-Party Certification*, and *Sanitary Transportation* rules all have application for the animal food industry. Of these four rules, the two with the broadest and most immediate implications are the *Preventive Controls for Animal Food* and *Foreign Supplier Verification Program* rules.
The three major FSMA rules that do NOT apply to animal food are the rules for *Preventive Controls for Human Food*, *Produce Safety*, and *Intentional Adulteration*.

There are separate training requirements and standardized curricula for some of the other rules. For example, there is a separate course for the *Preventive Controls for Human Food* rule. If a facility has ingredients or raw material that is human food by-product intended for as animal food, some of these human food rules may be relevant to consider. However, this curriculum will focus only on the *Preventive Controls for Animal Food* rule.



January 2011 saw the signing of FSMA by President Obama. The first version of the *Preventive Controls for Animal Food* rule was published as a proposed rule in October 2013. A supplemental proposal that provided revisions to the proposed rule was issued in September 2014, and the final rule was published on September 17, 2015.

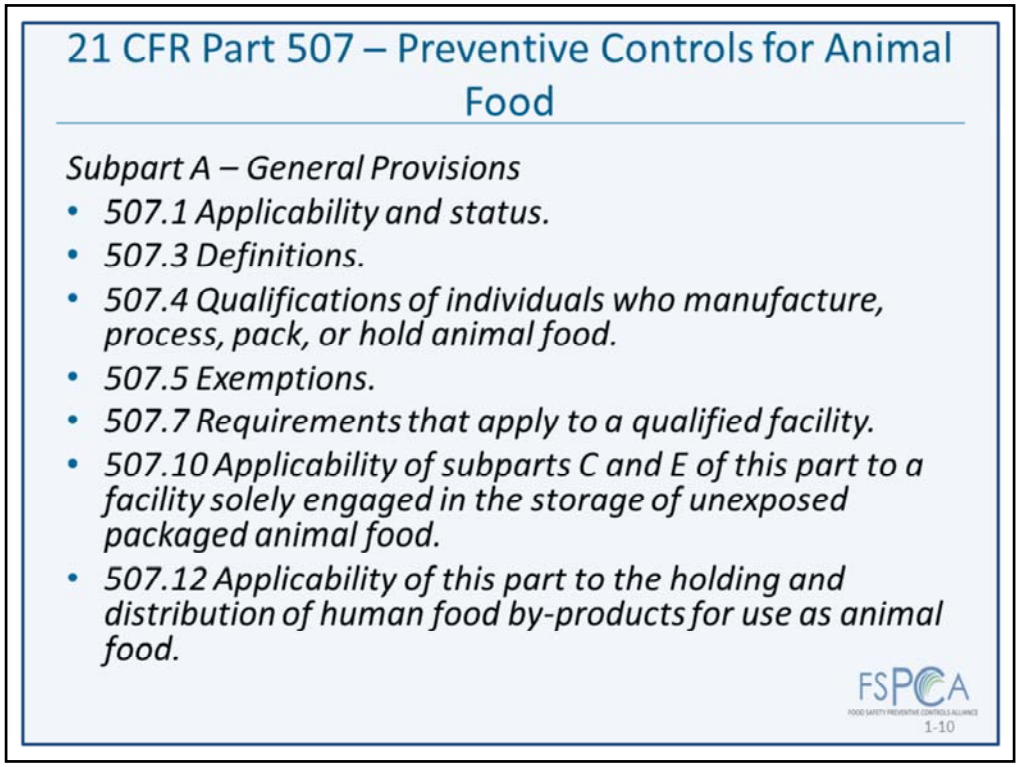
There are two major subparts to the rule – the Current Good Manufacturing Practice (CGMP) requirements found in 21 CFR part 507, subpart B and the Hazard Analysis and Risk-Based Preventive Controls requirements found in 21 CFR 507, subpart C. Because the animal food industry will be implementing both CGMPs and preventive controls for the first time, the compliance dates were staggered for the implementation of these subparts based on business size.
Businesses with more than 500 employees must comply with the Current Good Manufacturing Practice requirements by September 19, 2016 and the Hazard Analysis and Risk-Based Preventive Controls by September 18, 2017. Those meeting the definition of small businesses will have two years to comply with CGMP (September 18, 2017) and three years to comply with Hazard Analysis and Risk-Based Preventive Controls (September 17. 2018). Those that meet the definition of a *Very Small Business*, which includes a *Qualified Facility*, will have three years to comply with CGMP (September 17, 2018) and four years to comply with Hazard Analysis and Risk-Based Preventive Controls (September 17, 2019). Compliance

dates for another major subpart of the rule, subpart E (Supply-Chain Program) depend on several factors that will be described later in this course.

Here is the first slide with a blue outlined box and italics. That is a cue that the slide is referencing the regulation, not just examples or recommendations for its application. Note that this chapter has a lot of blue boxes as there will be a lot of regulatory concepts reviewed here. Other chapters tend to have less focus on the regulation as they are more focused in scope.

The *Preventive Controls for Animal Food* rule has 6 subparts (see Appendix 1 for a copy of the regulation in its entirety and Appendix 2 for a technical amendment to the rule). The subparts include:

- Subpart A: General Provisions, including training requirements and applicability
- Subpart B: Current Good Manufacturing Practice requirements
- Subpart C: Hazard Analysis and Risk-Based Preventive Controls
- Subpart D: Requirements for withdrawal of a *Qualified Facility*'s exemption status by FDA
- Subpart E: Supply-Chain Program requirements
- Subpart F: Requirements applying to records that must be established and maintained



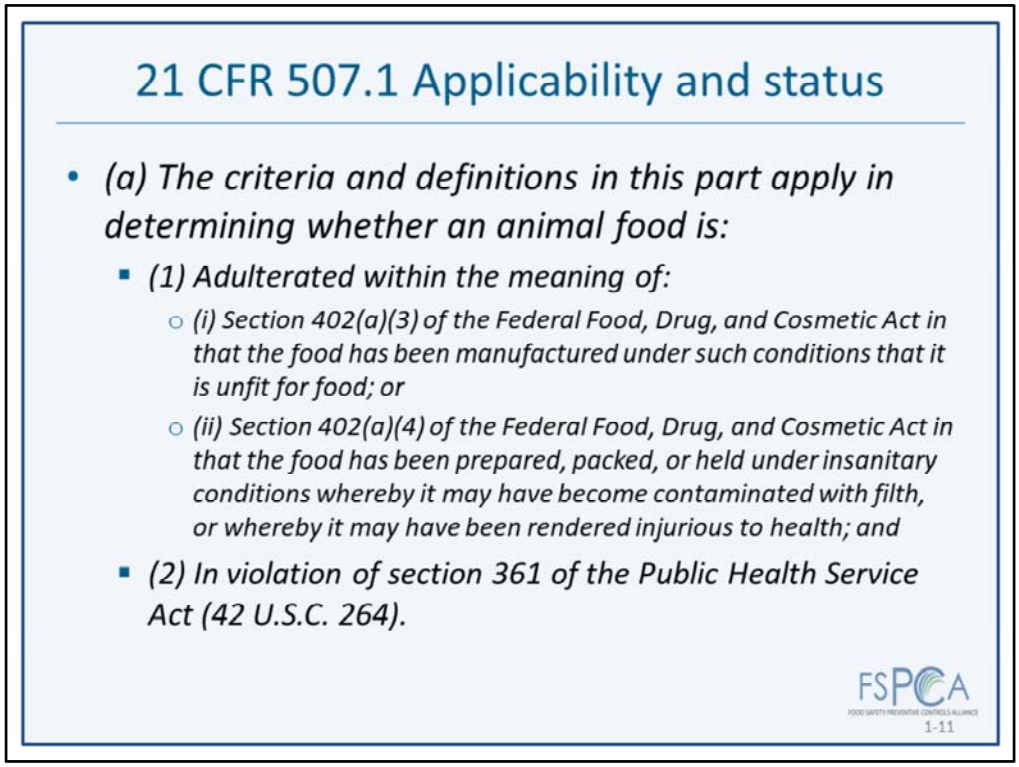
(The Preamble is where the FDA has provided additional context and answered the public comments to the *Preventive Controls for Animal Food* rule. If there are additional questions about a section of the regulations, it is often helpful to read the corresponding section of the Preamble. The Preamble reflects the FDA's current thinking of the time of rule writing.

Because the rule with the Preamble is 188 pages, only the 20 pages of codified language is included in this training material. The full Federal Register notice with Preamble can be found at https://www.gpo.gov/fdsys/pkg/FR -2015-09-17/pdf/2015-21921.pdf.)

The General Provisions in subpart A are broken into sections that describe the rule's applicability and status, definitions, qualifications of individuals who manufacture, process, pack, or hold animal food, exemptions, requirements that apply to a *Qualified Facility*, applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food, and applicability of this part to the holding and distribution of human food by-products for use as animal

food. Each of these sections will be described next.

It is suggested that participants follow along with the regulatory text in Appendix 1. The content of Appendix 1 is the final rule printed from the Federal Register. The whole rule in this format, including the Preamble, is 188 pages long according to the Federal Register. The last 20 pages are provided, which is the codified portion of the rule. The first section is Section 507.1, the Applicability and Status of the rule. That section begins on the first page of Appendix I, which is page number 56337 of volume 80 of the Federal Register.

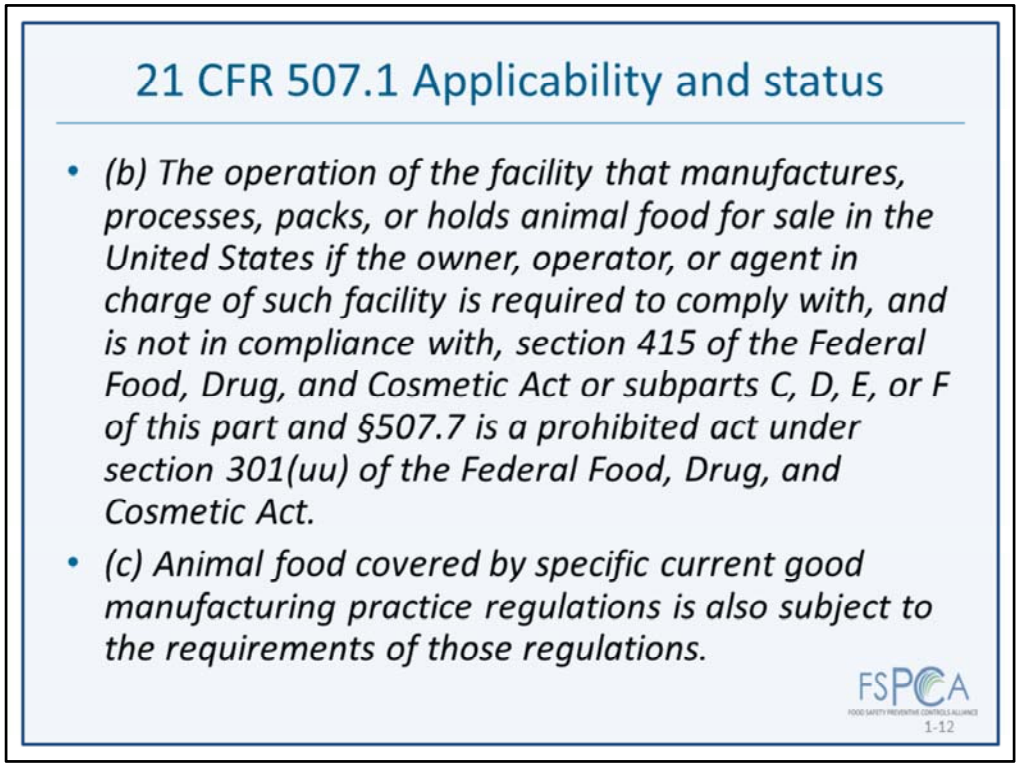


(The determination if specific facilities meet the applicability or exemptions described by the *Preventive Controls for Animal Food* rule is outside the scope of this course. Questions regarding applicability may be directed to the FDA via the online Technical Assistance Network portal available through: www.FDA.gov/fsma.)

An animal food does not need to contain a harmful substance to be adulterated. The Federal Food, Drug, and Cosmetic Act (Sections 301(a) and (k) prohibits introducing or delivering for introduction into interstate commerce adulterated animal food, and doing an act (e.g., violating CGMPs or preventive controls) that causes animal food to become adulterated after receipt of that food or its components in interstate commerce while the food is held by a facility for sale.

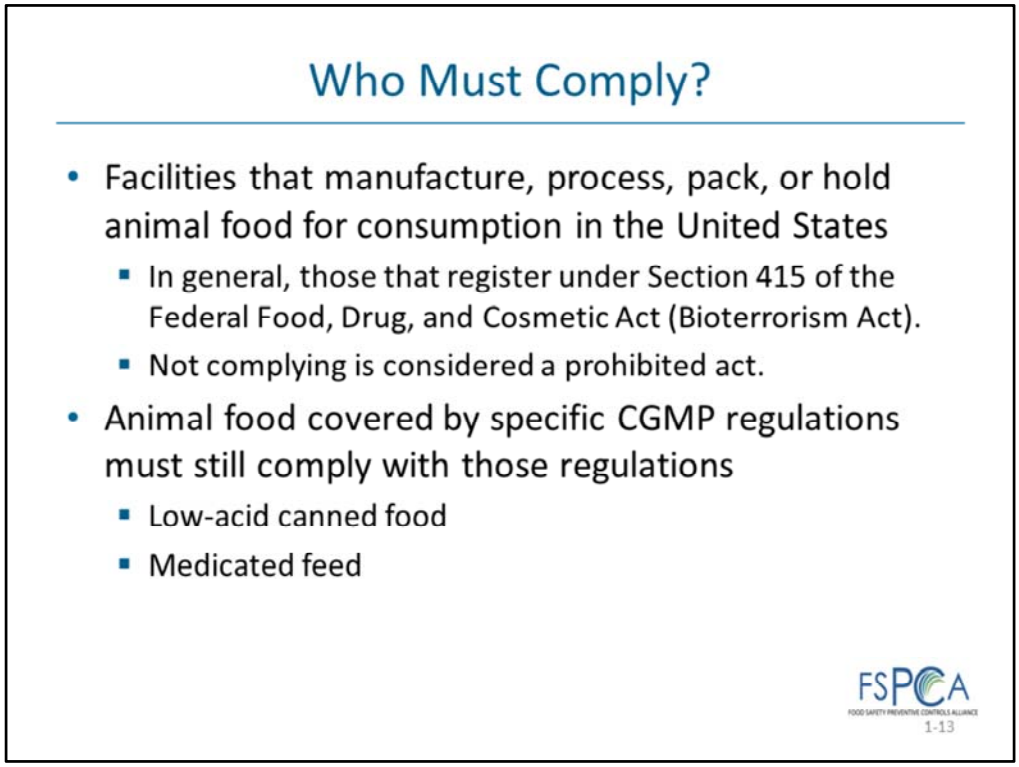
Among other remedies, the government has authority to file actions in court to remove adulterated animal food from the marketplace (seizure) and/or to prevent a firm from continuing to manufacture and distribute adulterated food (injunction; Sections 304 and 302). Following the CGMP requirements for animal food is important because it may help prevent you from producing and distributing adulterated animal food.

Ultimately, the failure to comply with the *Preventive Controls for Animal Food* rule may result in FDA determining an animal food is adulterated because it was manufactured under conditions unfit for food, or it was prepared, packed, or held under insanitary conditions where it may have been contaminated.

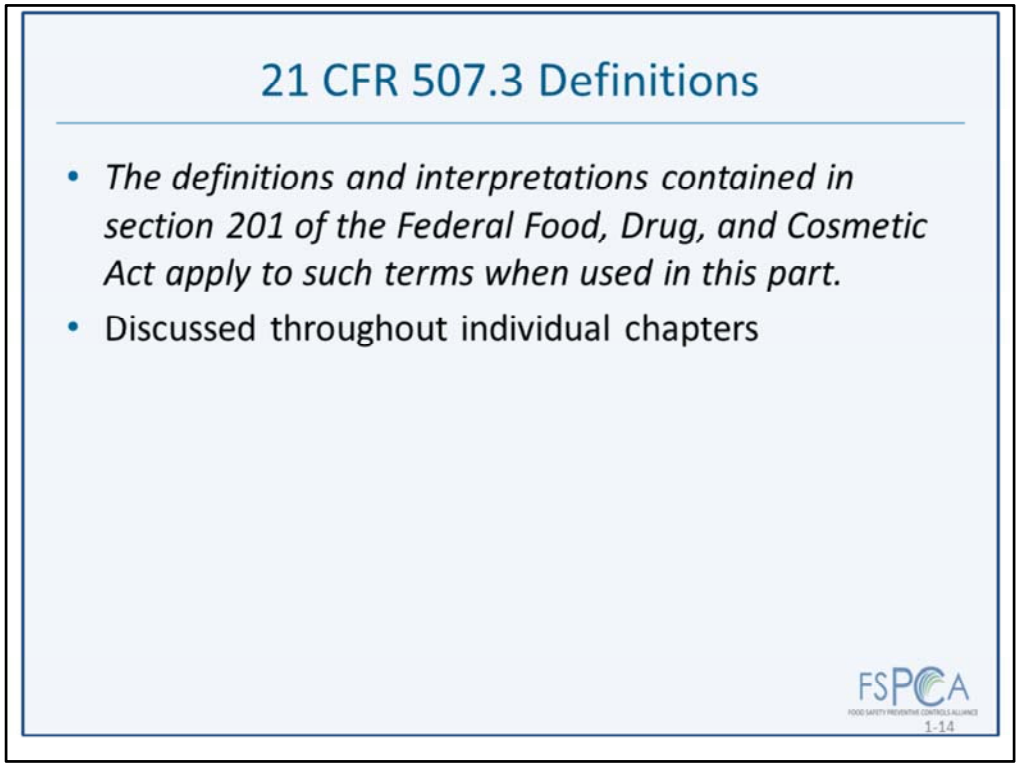


Preventive Controls for Animal Food rule applies to all facilities that are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act because they manufacture, process, pack, or hold animal food for consumption in the United States. There are some exemptions and modified requirements for certain registered facilities, which are discussed later. Establishments, such as farms, are exempt from registration and are therefore not subject to the requirements of 21 CFR part 507. Both domestic animal food manufacturing facilities and foreign facilities importing food into the U.S. must comply with the rule.

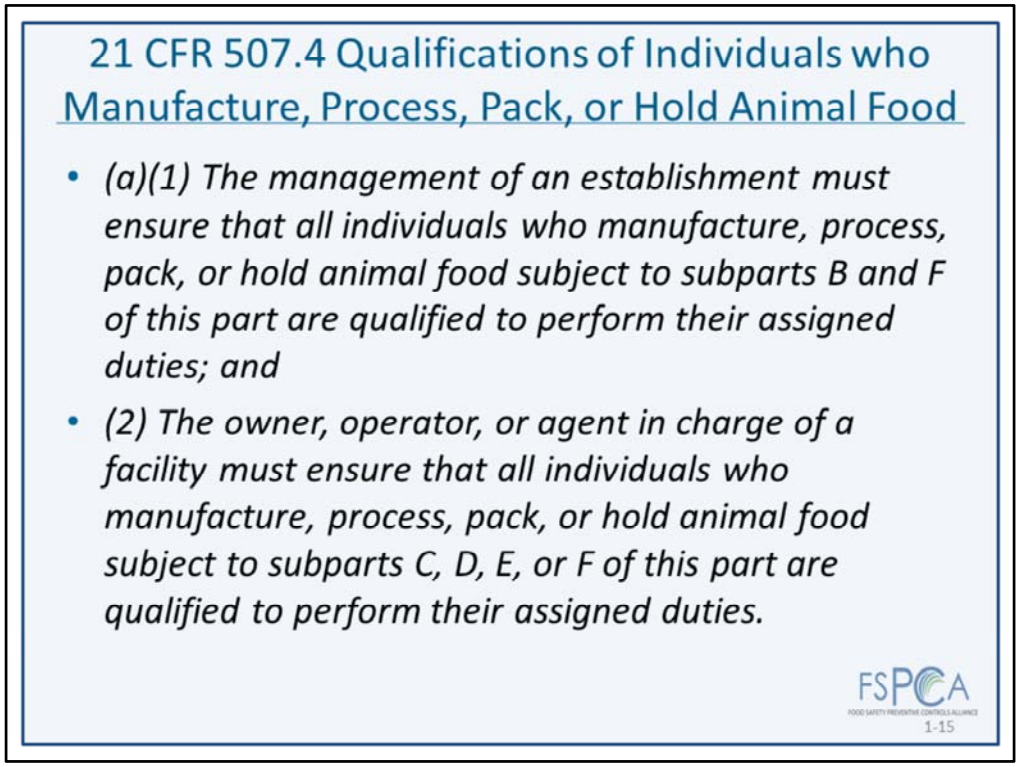
In addition to regulations outlined in this rule, facilities must still comply with other regulations that apply to the type of animal food they are manufacturing, such as regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR 113) and Current Good Manufacturing Practice for Medicated Feeds (21 CFR 225).



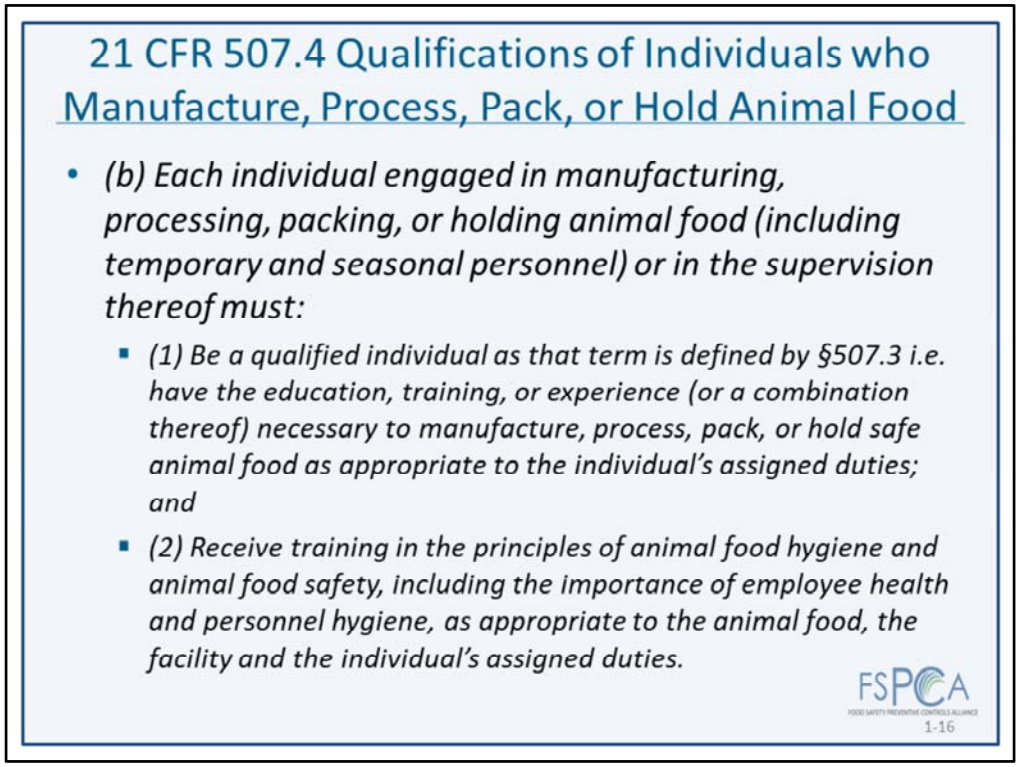
To summarize, the rule is applicable to facilities that register as an animal food facility under Section 415 of the Federal Food, Drug, and Cosmetic Act. If facilities do not comply, it is a prohibited act. Facilities that are already subject to other animal food safety regulations, such as medicated feed CGMPs, must continue to abide by those regulations in addition to the requirements found in the *Preventive Controls for Animal Food* rule.



The definitions found in 21 CFR 507.3 include the definitions found in section 201 of the Federal Food, Drug, and Cosmetic Act and the specific definitions that are also listed in 21 CFR 507.3. This curriculum will not walk through each definition in 21 CFR part 507. Instead, it will cover them as the need arises throughout the training. The official definitions begin on page 2 of Appendix 1, which is page 56338 of the Federal Register.

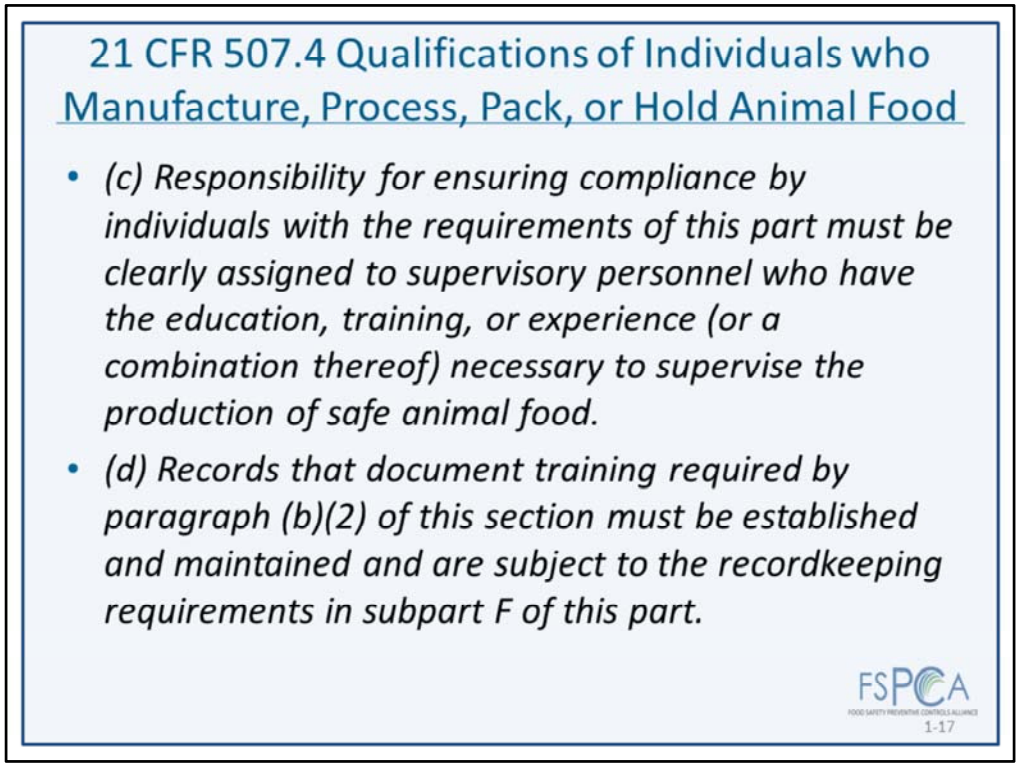


The next section describes the required qualifications of an individual who is directly involved in manufacturing, processing, packing, or holding animal food. For establishments subject to CGMP and record-keeping requirements (21 CFR part 507, subparts B and F), the management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties. For facilities subject to hazard-analysis and risk based preventive control, supply-chain program, and record keeping requirements (21 CFR part 507, subparts C, E, and F), the owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties.



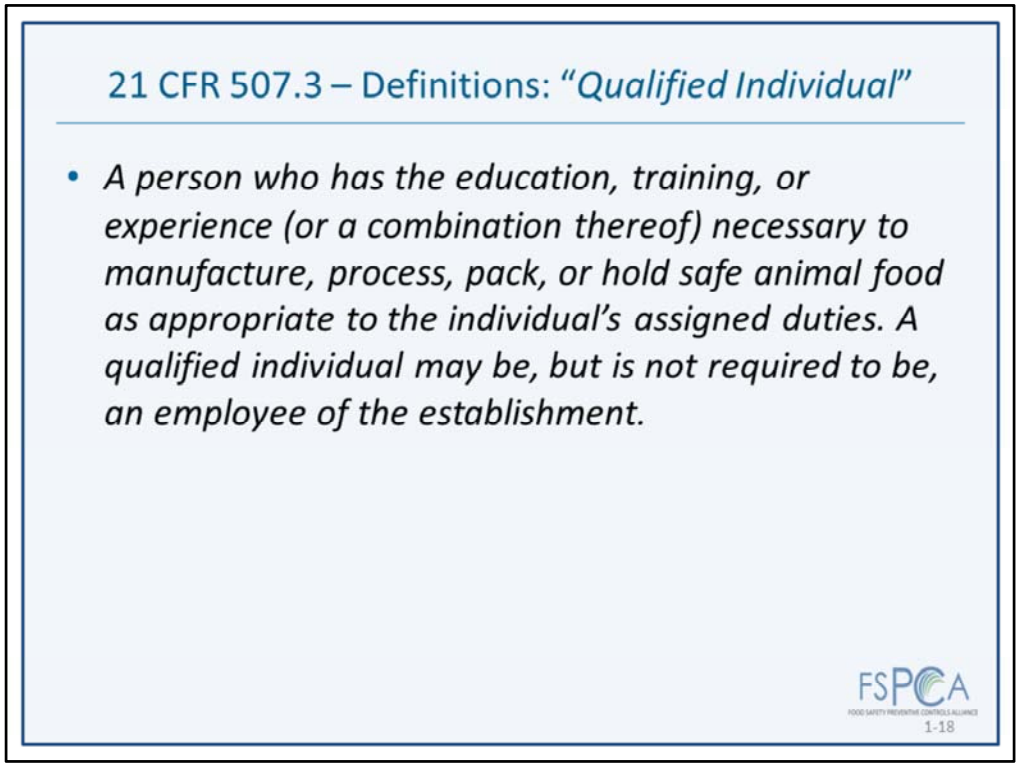
Any individual, including temporary and seasonal personnel, engaged in manufacturing, processing, packing, or holding of animal food or the supervision of those activities must be a *Qualified Individual* as defined in section 507.3. He or she must have the education, training, or experience, or a combination thereof, necessary to manufacture, process, pack or hold safe animal food as appropriate to the individual's assigned duties.

In addition, the individual must receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personnel hygiene, as appropriate to the animal food, the facility, and the individual's assigned duties.



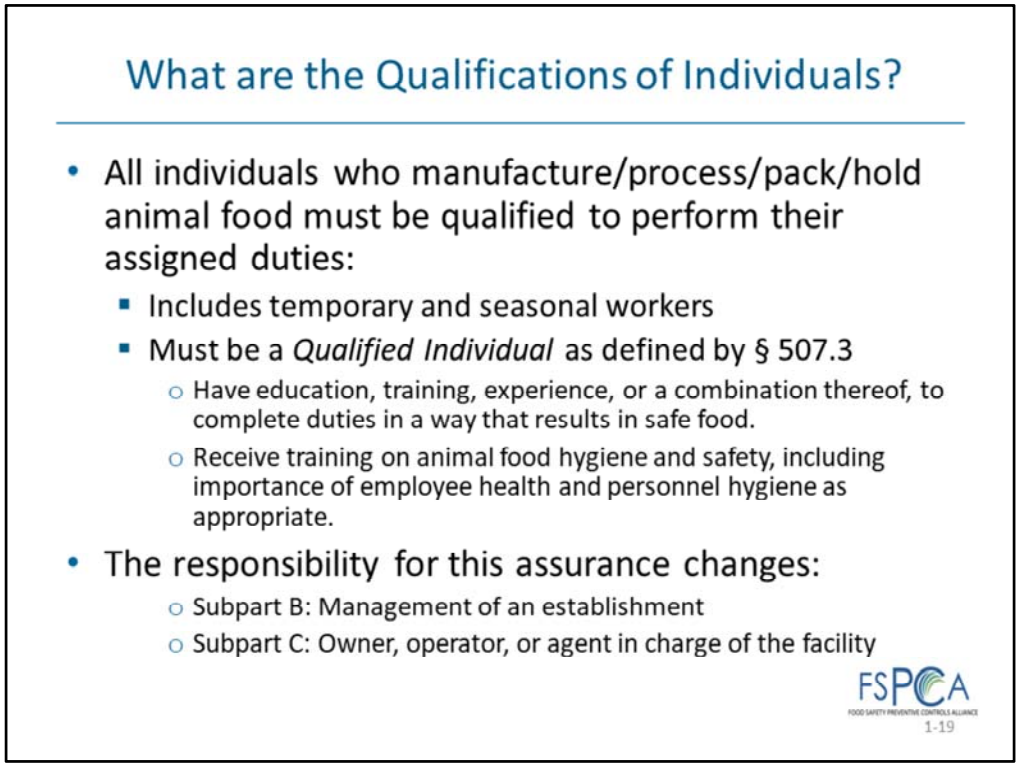
Supervisors must ensure compliance with training to the duties of the qualified individual and the training in principles of animal food hygiene and animal food safety.

Records must be established and maintained to document that the training in animal food hygiene and animal food safety occurred. Those records are subject to the requirements outlined in 21 CFR part 507, subpart F, which will be described at the end of this chapter.



Qualified Individual is a defined term in the definitions section of the rule. The requirements for training, established in subpart A, apply to individuals engaged in manufacturing, processing, packing, or holding food regardless of whether the individuals conduct these activities under the framework of the CGMPs established in subpart B or the framework for hazard analysis and risk-based preventive controls established in subparts C, D, E, and F.

Note that a *qualified individual* may or may not be an employee of an establishment. Individuals, even if he or she is a temporary or seasonal worker, must be qualified to perform their assigned duties.



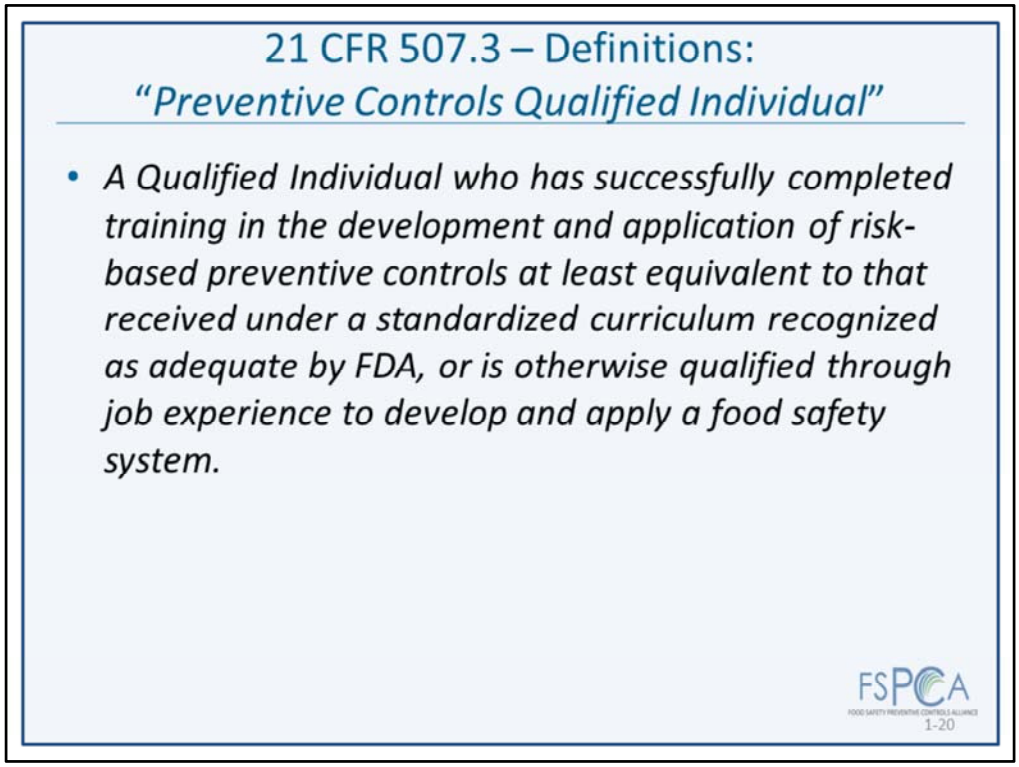
(The 'education or training' referred to in this section means training by any reasonable means. This may include training by facility personnel, an external source, or the combination of the two. Training may occur on the job, in a classroom setting, or online. There is no specified frequency for training, but individuals should receive training prior to independently performing their assigned duties and refresher training should be made available as appropriate.)

To summarize, all individuals associated with the specified tasks for animal food, even if they are temporary or seasonal workers, are required to be qualified in order to perform their assigned duties. The language that states "as appropriate to the animal food, the facility, and the individual's assigned duties" demonstrates that there is flexibility in the application of the requirement for training in the principles of animal food hygiene and animal food safety.

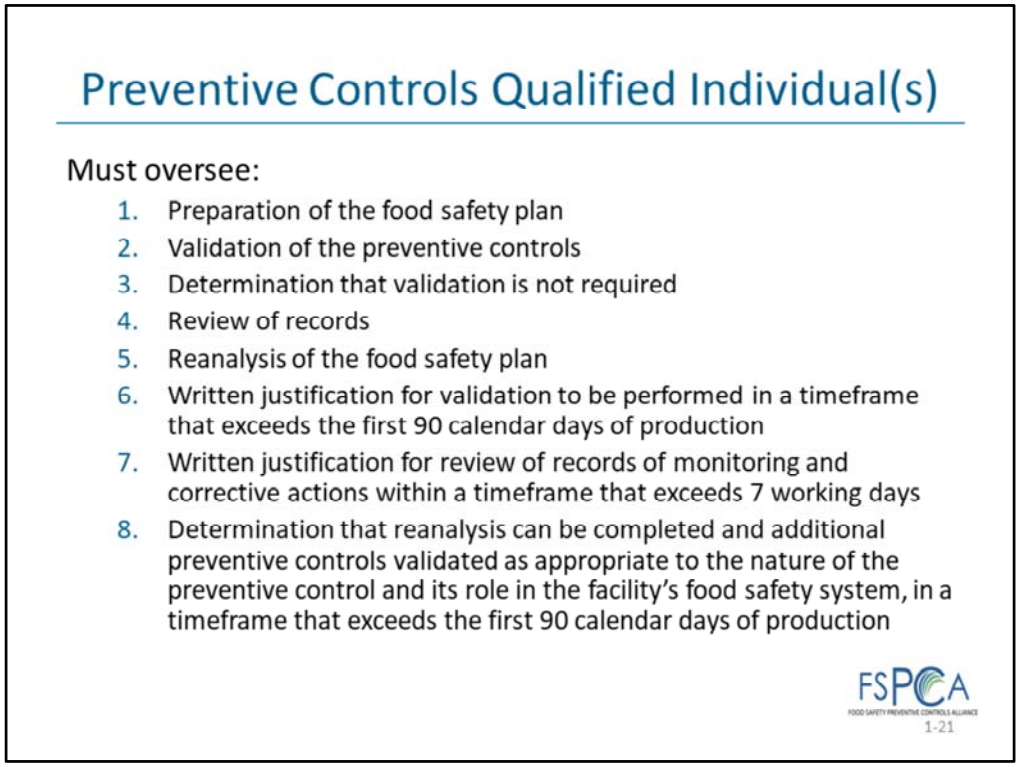
There may not be a need for all personnel to have the same level of training in the principles of animal food hygiene and animal food safety. For example, a forklift driver may not be required to undergo as intensive of a training course as an ingredient receiving operator. The forklift driver may rarely come in contact with unpackaged animal food, so his or her training may be geared towards what precautions to take when operating the forklift so that the animal food is not contaminated when it is being moved by the forklift. However, those individuals

must have the education, training, experience, or a combination thereof, to complete their duties in a way that results in safe animal food, and they must receive training on animal food hygiene and safety, including the importance of employee health and personnel hygiene, as appropriate. Records to support that training in animal food hygiene and safety are necessary for a facility to maintain.

Finally, the responsibility for the assurance that individuals are qualified changes depending upon the subpart. Management is responsible for assuring that individuals are qualified to perform their assigned duties when the plant is subject to the CGMP requirements in subpart B. Meanwhile, the owner, operator, or agent in charge of the facility is responsible for this assurance when the facility is subject to the requirements in subpart C, D, and E.

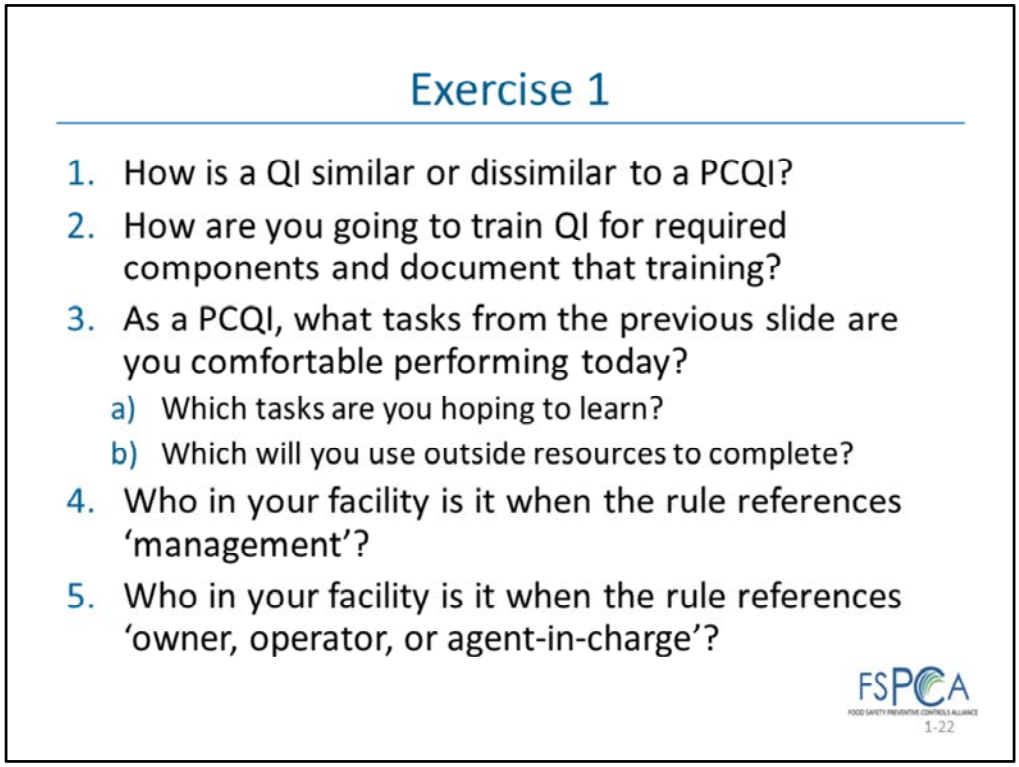


Another term that is similar to that of a *Qualified Individual* is a *Preventive Controls Qualified Individual*. This *Preventive Controls Qualified Individual* term will be described more fully in later chapters but is defined in 21 CFR 507.3 as a *Qualified Individual* who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that recognized under a standard curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.



Under the regulation (21 CFR 507.53), the *Preventive Controls Qualified Individual* has a lot of responsibility as certain tasks must be performed by someone with those qualifications. This course developed by FSPCA is the "standardized curriculum" recognized by FDA. Successfully completing this course is one way to meet the requirements for a *Preventive Controls Qualified Individual.* Under the *Preventive Controls for Animal Food* rule, some of the responsibilities of a *Preventive Controls Qualified Individual* include to perform or oversee 1) preparation of the food safety plan, 2) validation of the preventive controls, 3) records review and 4) reanalysis of the food safety plan.

The *Preventive Controls Qualified Individual* may be an employee of the facility but the facility can also use outside assistance in developing the food safety plan. In some situations, more than one *Preventive Controls Qualified Individual* may be needed to effectively develop and implement a food safety plan.


Exercise 1
1. How is a QI similar or dissimilar to a PCQI?
2. How are you going to train QI for required components and document that training?
3. As a PCQI, what tasks from the previous slide are you comfortable performing today?
a) Which tasks are you hoping to learn?
b) Which will you use outside resources to complete?
4. Who in your facility is it when the rule references 'management'?
5. Who in your facility is it when the rule references 'owner, operator, or agent-in-charge'?
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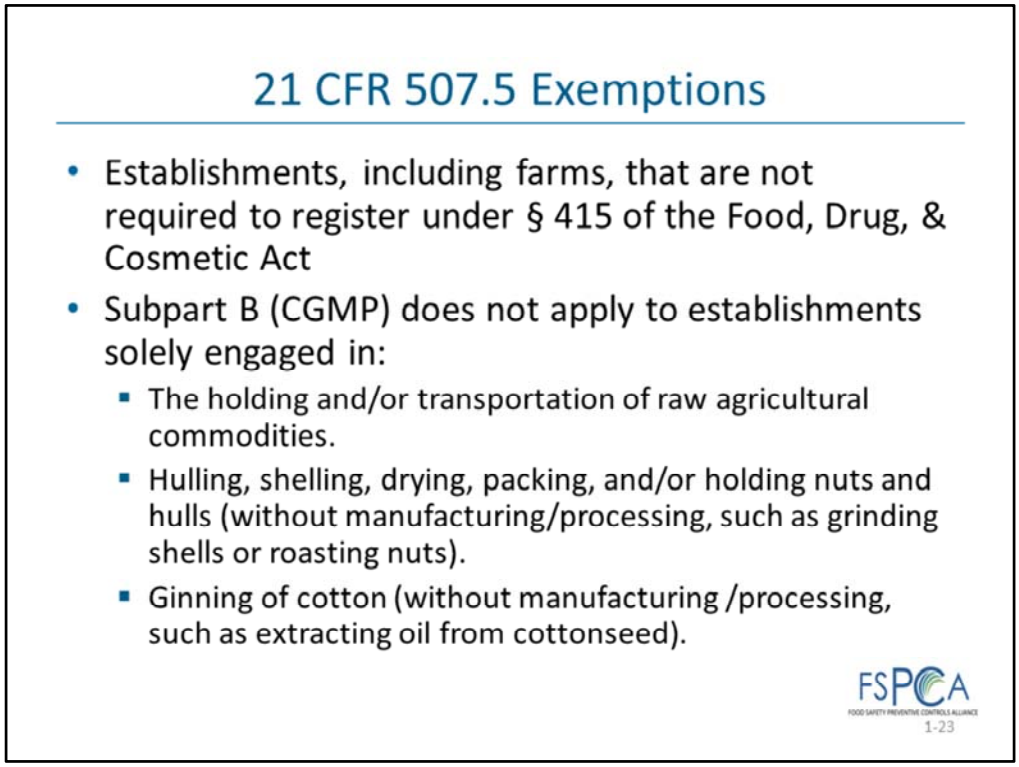
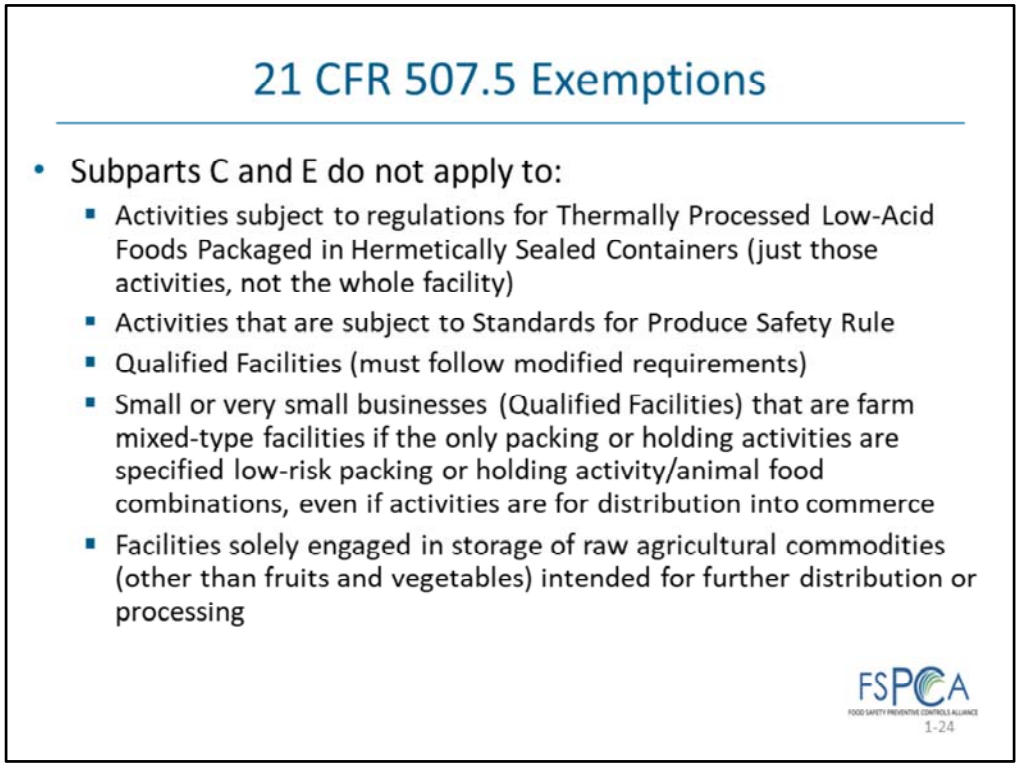
Exercise 1.



(As with the applicability section, the determination of whether specific facilities meet the exemptions described by the *Preventive Controls for Animal Food* rule is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum. Additional information is available in the rule. Questions regarding rule applicability may be directed to the FDA via the online Technical Assistance Network portal available through: www.FDA.gov/fsma.)

The next section of this chapter is key to understanding who is subject to the *Preventive Controls for Animal Food* rule. Exemptions to the rule or to specific subparts of the rule are found in 21 CFR 507.5. Establishments, such as farms, that are not required to register under section 415 of the Federal Food, Drug, & Cosmetic Act do not need to comply with any part of this rule. The definition of a farm is discussed in more detail later in this chapter. Other establishments that are not required to register include facilities such as retail food establishments, restaurants, pet shelters, and veterinary facilities that provide food to animals.

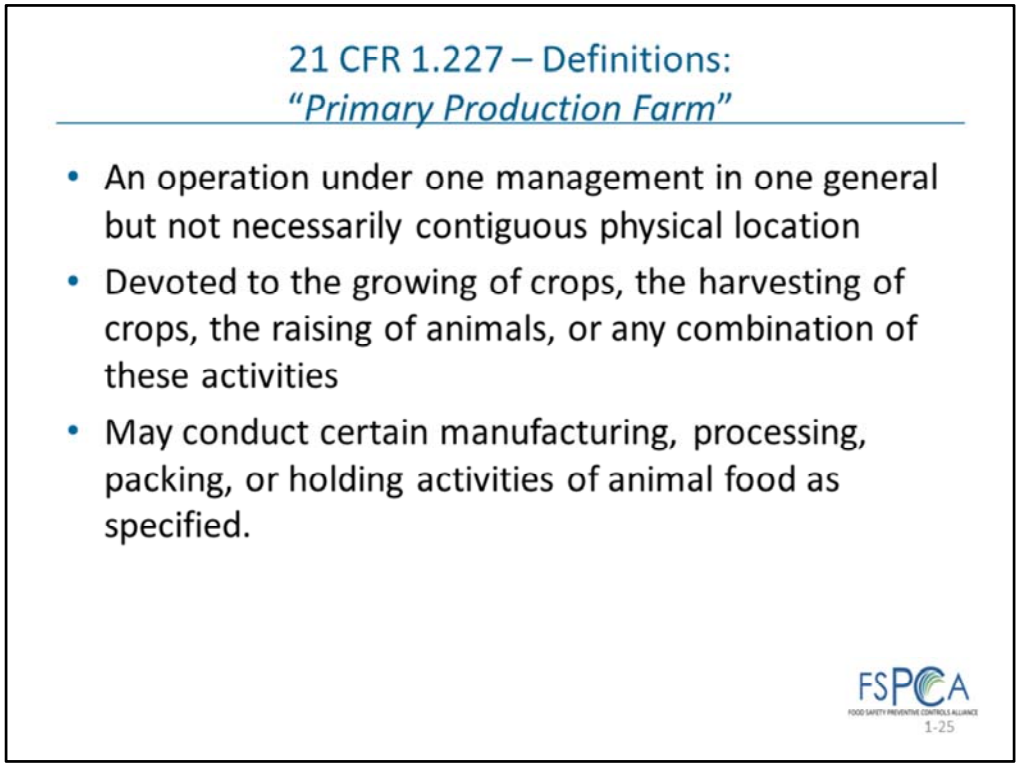
Subpart B, or the Current Good Manufacturing Practices, are not required for facilities that are (1) solely engaged in the holding and/or transportation of raw agricultural commodities, (2) the hulling, shelling, drying, packing, and/or holding of nuts and hulls (without manufacturing/processing), or (3) the ginning of cotton (without manufacturing/processing).



Finally, the hazard analysis and risk-based preventive controls and supply-chain program, which are subparts C and E, do not apply to:

1) Activities subject to regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers for the control of microbiological hazards
2) Activities that are subject to the produce safety rule.
3) A *Qualified Facility*. This definition will be discussed in subsequent slides. While qualified facilities are not subject to 21 CFR part 507, subparts C and E, there are modified requirements applicable to qualified facilities in 21 CFR 507.7.
4) A *Small Business* or *Very Small Business* that are farm mixed-type facilities if the only packing or holding activities are specified low-risk packing or holding activity/animal food combinations, even if the activities are intended to distribute animal food into commerce (for a list of activities, refer to 21 CFR 507.5(e) and (f)).
5) Facilities solely engaged in the storage of raw agricultural commodities (other

than fruits and vegetables) intended for further distribution or processing.



(Note these definitions come from the *Preventive Controls for Human Food (PCHF)* rule, as seen by the different CFR reference. The exact definitions can be found in the PCHF rule, and additional explanation of their applicability can be found in the Preamble of that rule.

The clause that requires "all processed food to be consumed on the farm or another farm under the same management" is key to understanding applicability of the *Preventive Controls for Animal Food* rule to feed mills that may be managed by a farm.)

To be subject to the requirements of the *Preventive Controls for Animal Food* rule, a facility has to be required to register under section 415 of the Food, Drug, and Cosmetic Act. Farms are one type of establishment that are not subject to registration and are therefore exempt from the requirements of this rule. Farms are defined in 21 CFR 1.227. The definition of a farm is broken into two parts, a *Primary Production Farm* and a *Secondary Activities Farm.* The *Primary Production Farm* is

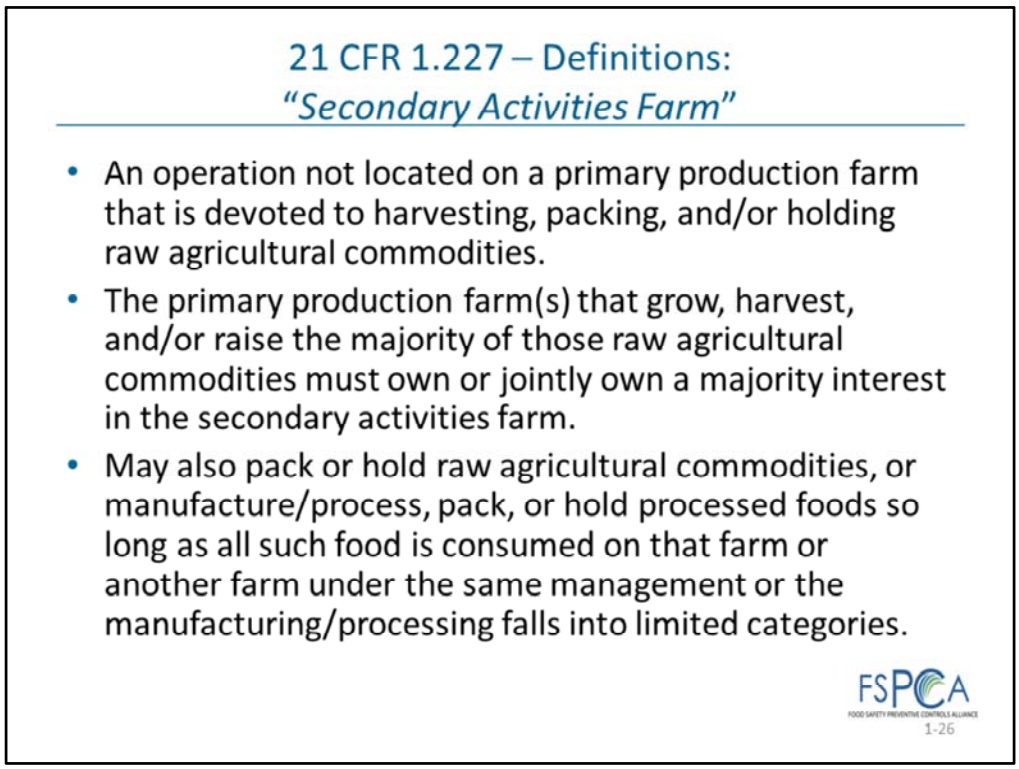
an operation under one management in one general, but not necessarily contiguous, location that is devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities.

This definition includes operations that:

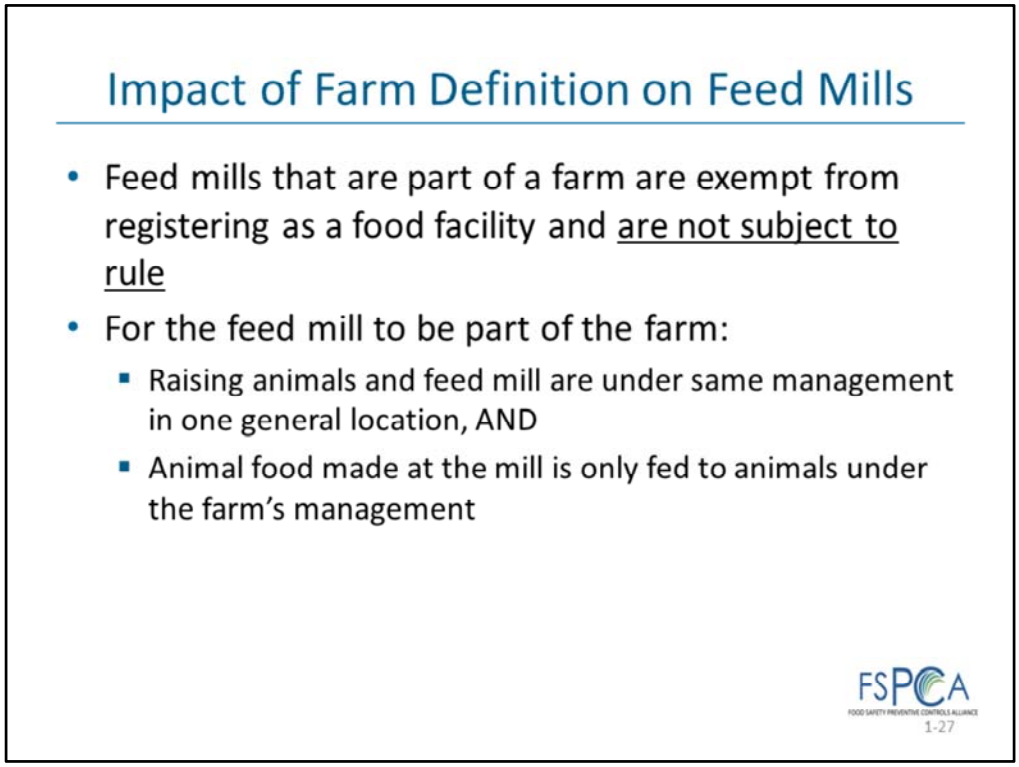
1) Pack or hold raw agricultural commodities;
2) Pack or hold processed foods, provided that all processed food is consumed on the farm or another farm under the same management; or
3) Manufacture/process food, provided the activities fall into limited categories, such as

a. A processed food that is a distinct commodity created from drying/dehydrating raw agricultural commodities to create a distinct commodity;
b. Treatment to manipulate ripening; or
c. Packaging and labeling without additional manufacturing/processing.

The raising of animals is outside of the scope of the *Preventive Controls for Animal Food* rule – that is clearly a farming activity. The rule is specific to the manufacturing, processing, packing, or holding of animal food – so the feed mill located on the farm is the part of a farm that is potentially subject to the rule.



The *Secondary Activities Farm* was created to address off-farm operations, such as packinghouses owned by farmers. A *Secondary Activities Farm* is an operation not located on a *Primary Production Farm*, but is dedicated to the harvesting, packing, and/or holding of raw agricultural commodities. The *Secondary Activities Farm* must be majority owned by the *Primary Production Farm*(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, or held by the *Secondary Activities Farm.* A *Secondary Activities Farm* may also conduct activities that are allowed on a *Primary Production Farm*.



(In the future, it is expected a proposed rule will require some feed mill operations that currently are part of a farm to implement the Current Good Manufacturing Practices established by the *Preventive Controls for Animal Food* rule.

For a full discussion of changes to the farm definition, refer to the Preamble to the *Preventive Controls for Human Food* rule (pages 55925 to 55932 of vol. 80 of the Federal Register).

For a full discussion of 'fully vertically integrated farming operations' refer to the Preamble to the Preventive Controls for Animal Food rule (pages 56184-56185 of vol. 80 of the Federal Register).)

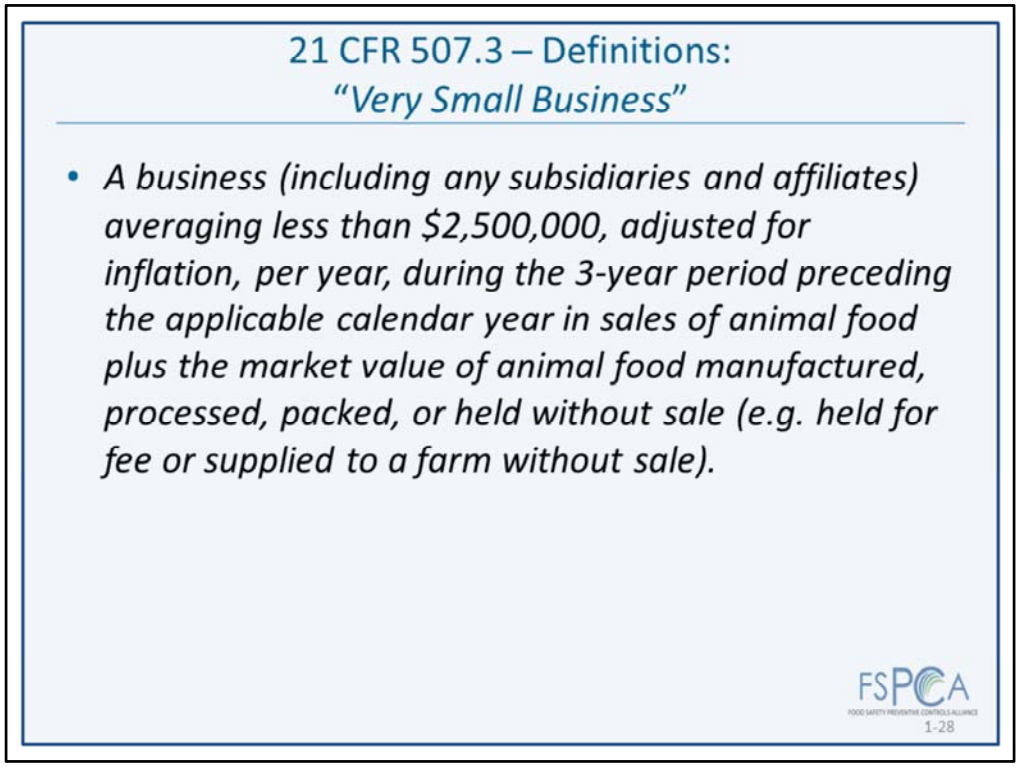
Feed mills that manufacture or process animal food have the potential to be subject to the requirements of this final rule. If a feed mill is part of the farm – meaning the

feed mill and raising the animals are under the same management, in one general location, and the animal food made at the feed mill is only fed to animals under the farm's management -that feed mill is exempt from registering as a food facility as it falls under the definition of a farm. In the preamble to the final rule, FDA describes this type of farming operation as a "fully vertically integrated farming operation." Because these types of feed mills are not subject to registration, these feed mills are NOT subject to any part of the rule (CMGPs or preventive controls).

On the opposite side, there are feed mills that are required to register as a food facility under section 415 of the Federal Food, Drug, & Cosmetic Act and are subject to the *Preventive Controls for Animal Food* rule. There are several examples of feed mills required to register, but three key examples include:

1) Commercial or toll mills: The mill produces animal food for sale and is not associated with a farm. The feed mill must register as a food facility and is subject to the rule.
2) Feed mill located off-farm that makes animal food for contract farms – These feed mills are not under the same management as the farms that are responsible for the raising of animals. The feed mill must register as a food facility and is subject to the rule.
3) Farm feed mill with outside customers: The feed mill manufactures food for animals on the farm and under the same management, but also manufactures, processes, packs, or holds food for animals on farms under a different management. The mill must register as a food facility and is subject to the rule.

These are examples of feed mills that are not considered part of farm and are required to register as a food facility. Therefore, these feed mills are subject to the rule.

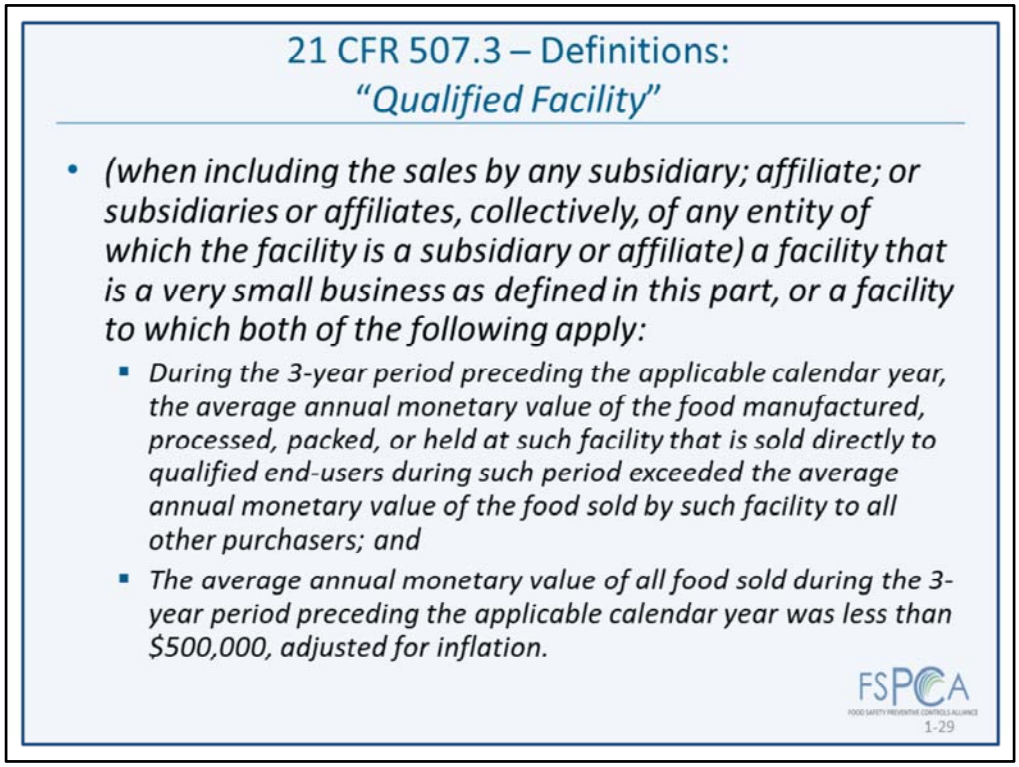


(As with the exemption section, an in-depth discussion of business sizes and of a Qualified Facility is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum. Additional information is available in the rule or the FDA Guidance for Industry regarding Qualified Facilities. Additional questions regarding rule applicability may be directed to the FDA Technical Assistance Network.)

If a facility does not meet the exemptions described by the farm definitions and registers as a food establishment, it must comply with the *Preventive Controls for Animal Food* rule. However, there are some additional exemptions and delayed compliance dates for *Qualified Facilities*. A *Very Small Businesses* is one type of *Qualified Facility.*

A *Very Small Business* is a business (including any subsidiaries and affiliates) 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, such as that held for a fee or supplied to a farm without sales.



(A guidance document for *Qualified Facilities* has been developed by the FDA. The guidance document provides information to assist facilities with determining whether they are a *Very Small Business,* including how to calculate the inflation adjusted average and market value. A discussion of how to value animal food without sale can be found in the Preamble of the *Preventive Controls for Animal Food* rule.

There is a definition for the *Qualified End-User,* referenced here *Qualified end-user*, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in §1.227 of this chapter) that:

(1) Is located:
   a. In the same State or the Same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment or
   b. Not more than 275 miles from such facility; and

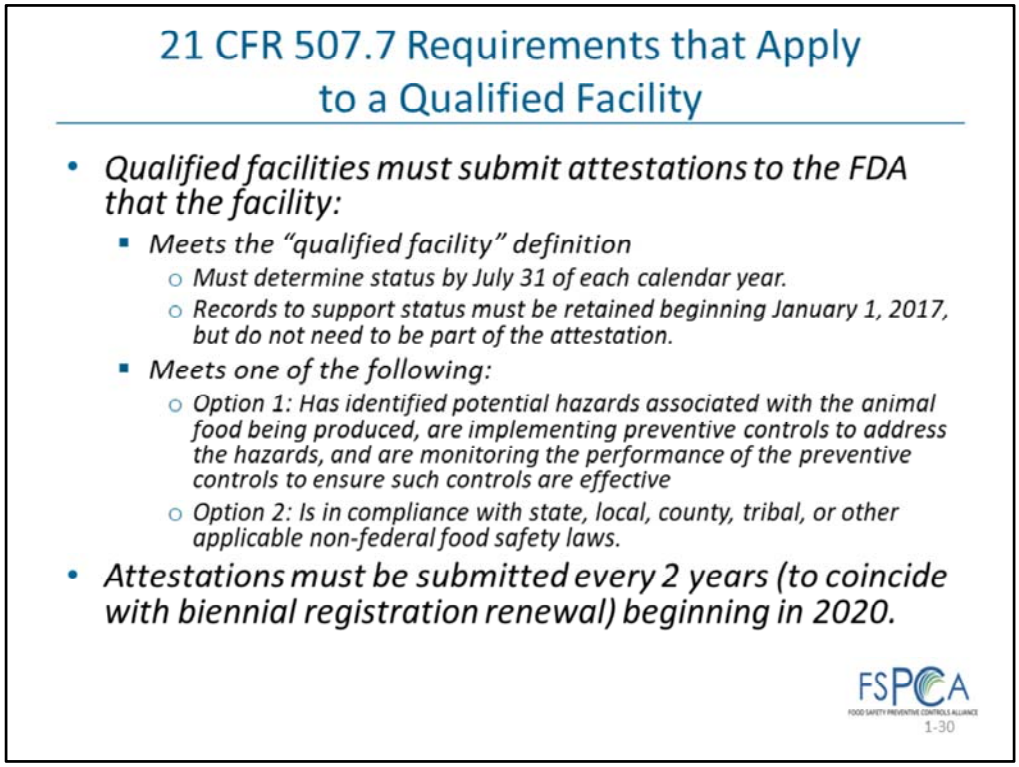
(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.)

A *Qualified Facility* is a facility that is a

- *Very Small Business*; **OR**
- A facility to which both of the following apply:

1. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchases; and
2. The average annual monetary value of all food sold during the 3-year prior preceding the applicable calendar year was less than $500,000, adjusted for inflation.

The majority of animal food facilities that meet the definition of a *Qualified Facility* are expected to be a *Very Small Business*, and not many animal food facilities are expected to meet the second half of the *Qualified Facility* definition.

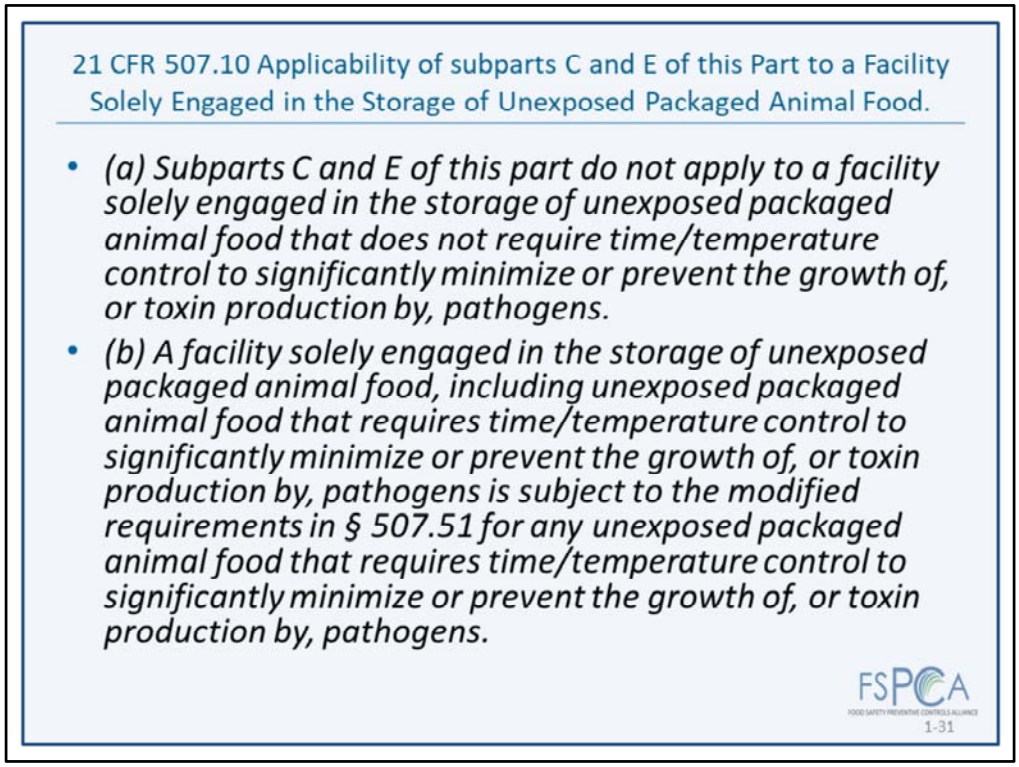


Qualified Facility must comply with the Current Good Manufacturing Practices in subpart B, but is exempt from hazard analysis and risk-based preventive controls (21 CFR part 507, subpart C) and requirements for a supply-chain program (21 CFR part 507, subpart E). However, the facility is subject to other specific requirements that are found in 21 CFR 507.7. Some may refer to these requirements as "modified requirements."

A *Qualified Facility* must submit required attestations to the FDA. The first attestation that the facility must submit is that it meets the definition of a *Qualified Facility*. Each qualified facility must determine its own status by July 31 of each calendar year, and the records to support this status must be retained beginning January 1, 2017. The facility must maintain the records (such as financial documents) to support that status. These records may include the three year average of sales that qualify them as a *Very Small Business* or *Qualified Facility* status. These records do not have to be sent to FDA as part of the attestation.

The facility has a choice between two options for its second attestation. Option 1 is an attestation that the facility has identified potential hazards in its animal food and is implementing, and subsequently monitoring preventive controls. Option 2 is an attestation that the facility is in compliance with state, local, county, tribal, or other applicable non-Federal food safety law.

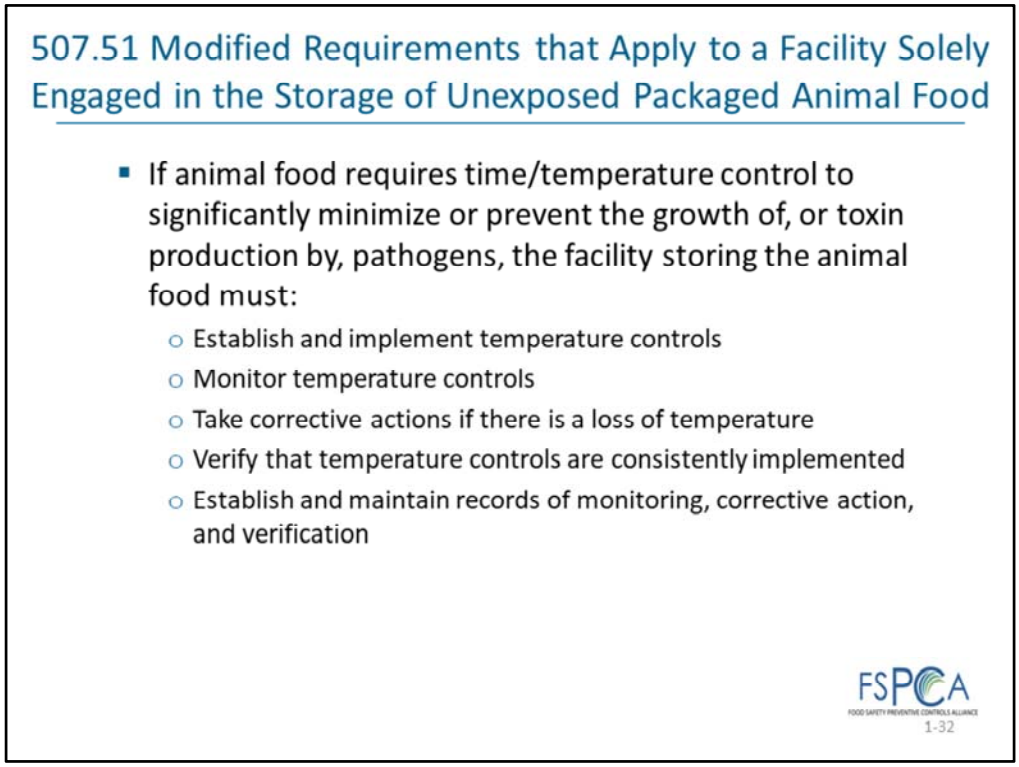
The first time a *Qualified Facility* must submit its initial attestation is by December 16, 2019. After the initial attestation, attestation must be submitted every 2 years (to coincide with the biennial registration renewal) beginning in 2020.



Section 507.10 of the regulation discusses the applicability of the requirements for hazard analysis and risk-based preventive controls (subpart C) and the supply-chain program requirements (subpart E) to facilities that are "solely engaged in the storage of unexposed packaged animal foods," such as warehouses.

If a warehouse's only function is to store unexposed packaged animal food that does not require time/temperature control to control pathogens – the warehouse is exempt from the requirements for subparts C and E.

If a warehouse's only function is to store unexposed packaged animal food that does require time/temperature control to control pathogens – the warehouse is exempt from the full requirement s of subparts C and E, but the warehouse would be subject to the modified requirements for this type of facility as specified in 21 CFR 507.51(b) as outlined next.



(As with the exemption section, an in-depth discussion of these modified requirements is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum. Additional information is available in the rule. Questions regarding rule applicability may be directed to the FDA via the online portal available through: www.FDA.gov.)

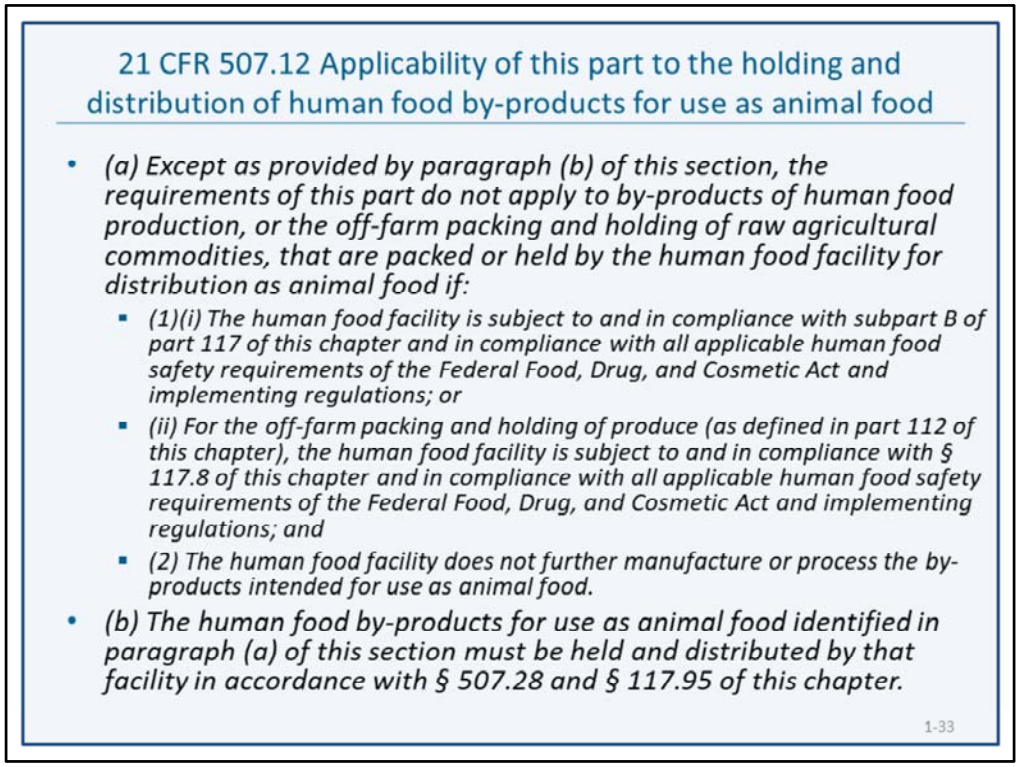
Animal food facilities, such as a warehouse, that are solely engaged in storage of unexposed packaged animal food that requires time/temperature controls to control a pathogen are not subject to the full requirements of subpart C and E. Instead they are subject to modified requirements as specified in 21 CFR 507.10(b).

If animal food requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, the facility storing the animal food must:

- Establish and implement temperature controls that can control the growth (or

toxin formation) of a pathogen.

- Monitor the implemented controls at a frequency determined to be adequate by the facility.
- Take corrective actions if there is a loss of temperature.
- Verify that temperature controls are consistently implemented.
- Establish and maintain records of monitoring, corrective action, and verification.



The next section clarifies the applicability of subparts B, C, and E to the holding and distribution of human food by-products for use as animal food.

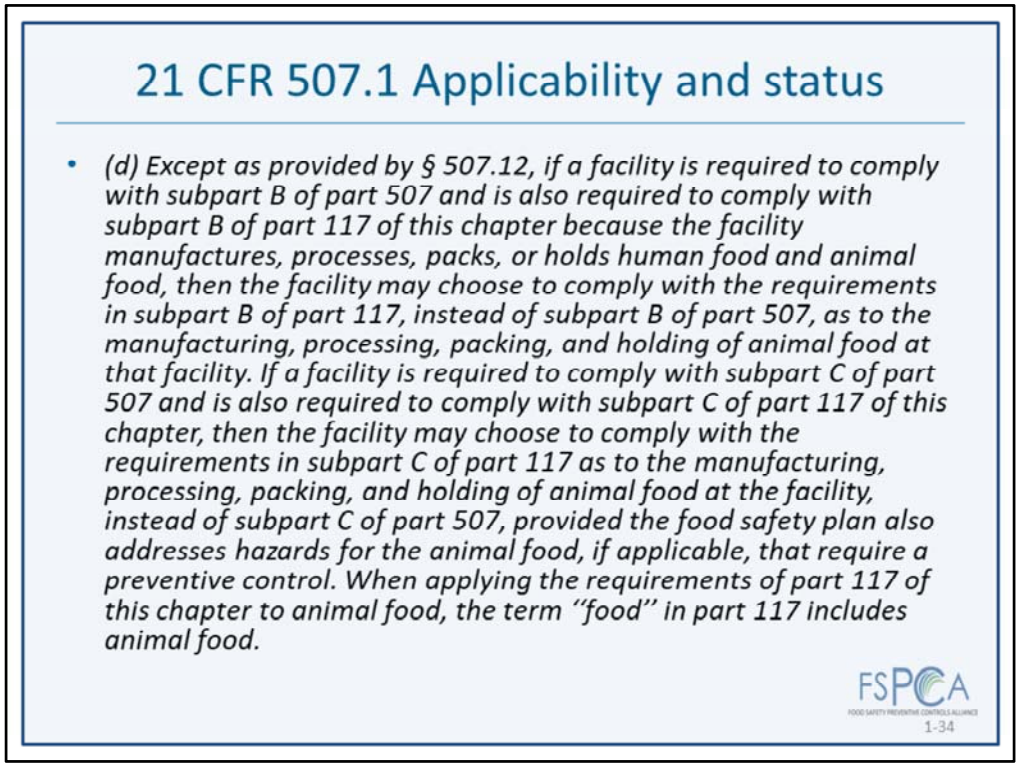
If a human food facility is producing a human food by-product for distribution as animal food, and:

- 1) the animal food is subject to and in compliance with the human food CGMP regulations (21 CFR part 117), and
- 2) The facility does not further manufacture or process the by-products intended for use as animal food,

Then the facility must follow limited holding and distribution CGMP requirements from 21 CFR 507.28 after the animal food has been separated from the human food. The facility would not need to follow the rest of the requirements in subpart B, C, or E for part 507.

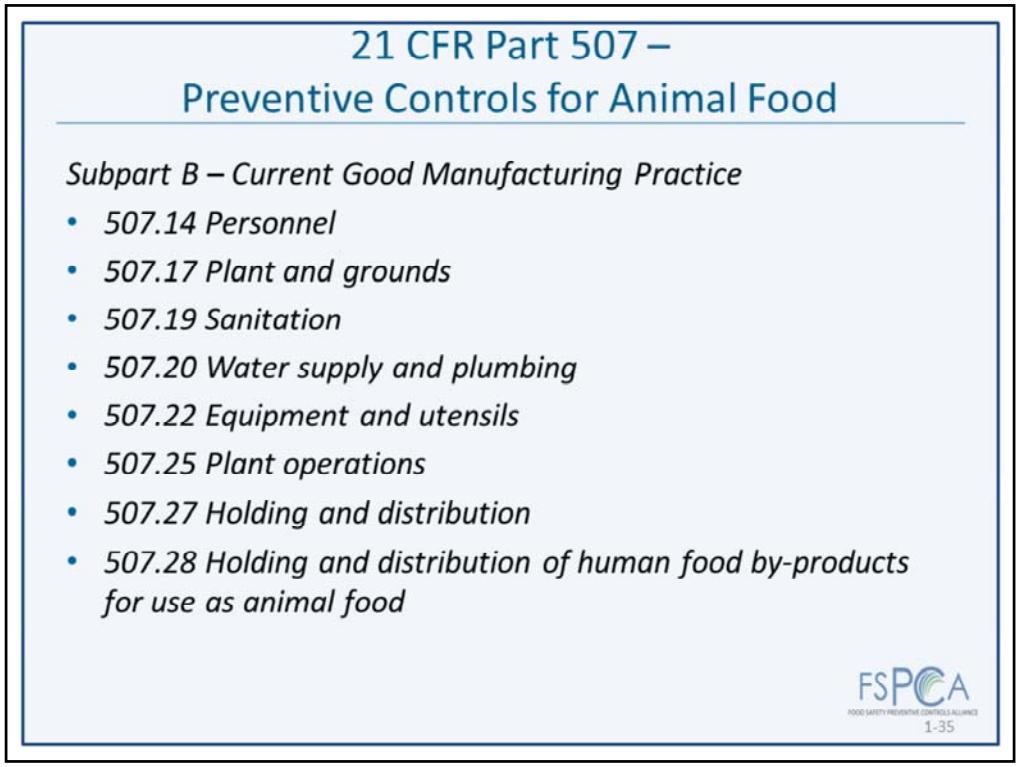
The holding and distribution of human food by-product for use as animal food requirements are located in both the human food requirements (21 CFR 117.95) and the animal food requirements (21 CFR 507.28).

There is a similar provision regarding by-products from facilities that are subject to and in compliance with the requirements for off-farm packing and holding of human food produce that are distributed for use as animal food.

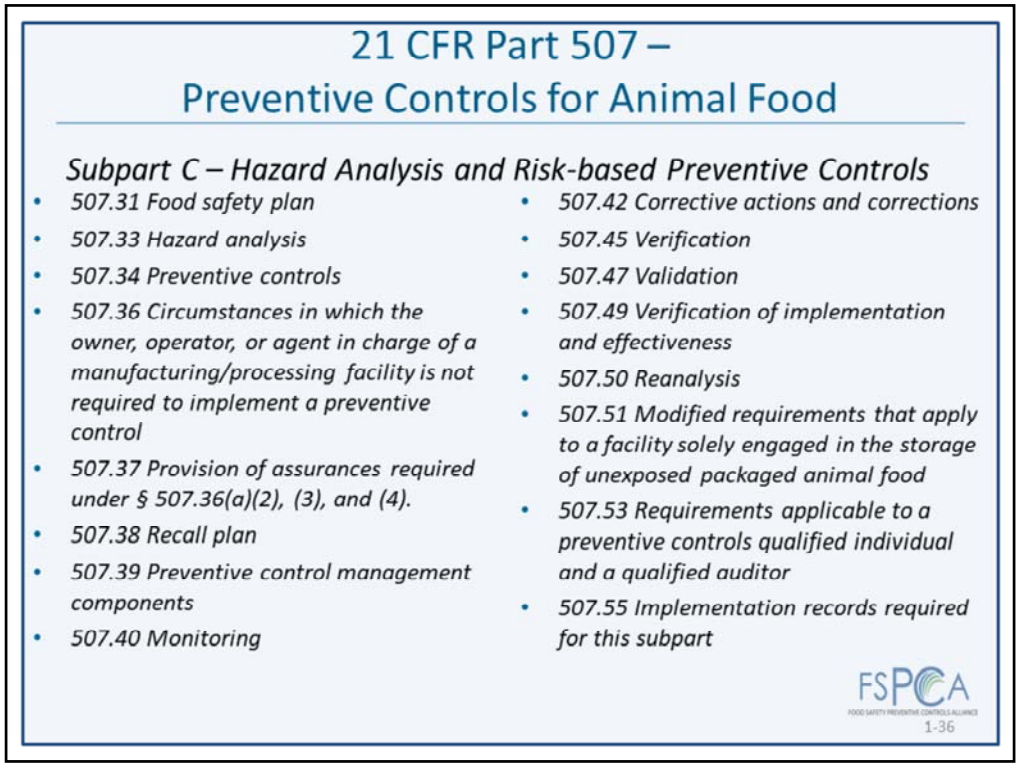


For facilities that do not meet the conditions described in 507.12 from the previous slide and are producing human and animal food at their facility, they have the option of following the human food CGMPs and preventive controls requirements in 21 CFR part 117 or the animal food requirements in part 507 for the production of their animal food. Depending on its operations, a facility may feel it is more appropriate to follow one set of regulations instead of two.

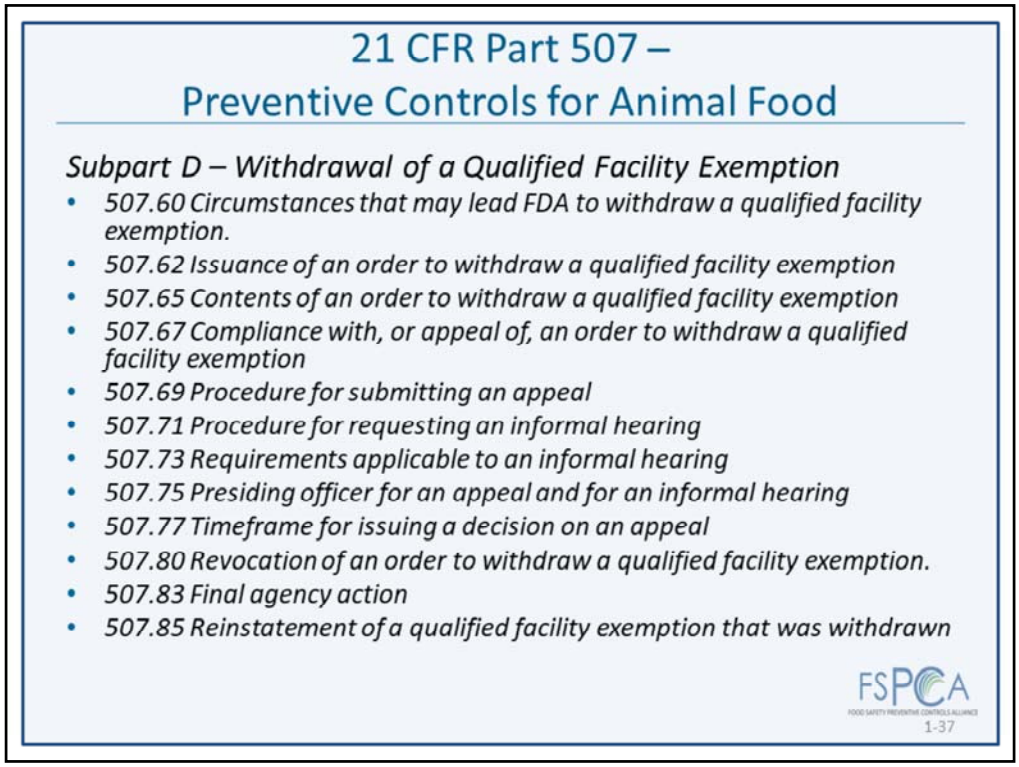
For example, if a facility has separate employees, production lines, and holding areas for its human food and animal food, it might prefer to follow part 117 for the human food and part 507 for the animal food. However, if a facility is using common employees, production lines, or holding areas for the human and animal food, it might prefer to follow part 117 for both the human and animal food.



That concludes subpart A, but there are six subparts total. Subpart B will have its own chapter and it will be discussed in Chapter 2. Chapter 2 describes the Current Good Manufacturing Practice requirements.



Most of the remaining curriculum will focus on subpart C, the hazard analysis and risk-based preventive controls requirements. There are many requirements to this subpart, and they will be discussed in detail in the coming chapters.



Subpart D explains the circumstances that may lead to FDA's withdrawal of a facility's *Qualified Facility* exemption, the process of the withdrawal, and processes and procedures that a facility must undergo to have its *Qualified Facility* status reinstated.

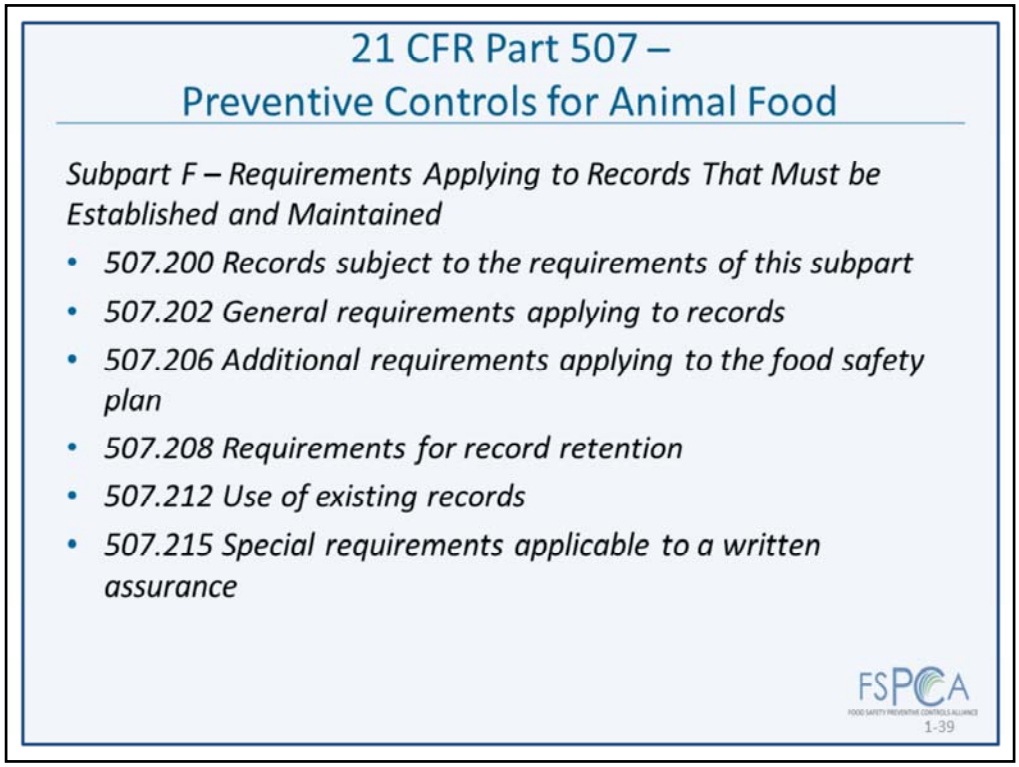
The FDA may withdraw a *Qualified Facility* exemption if: 1) there is an active investigation of a foodborne illness outbreak directly linked to the *Qualified Facility*; or 2) FDA determines it is necessary to protect the public human or animal health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the *Qualified Facility* that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

Generally, *Qualified Facility* have an exemption from the requirements of subpart C and E and are instead subject to other requirements for a *Qualified Facility* found in 21 CFR 507.7. However, if a problem occurs, FDA has the ability to withdraw the

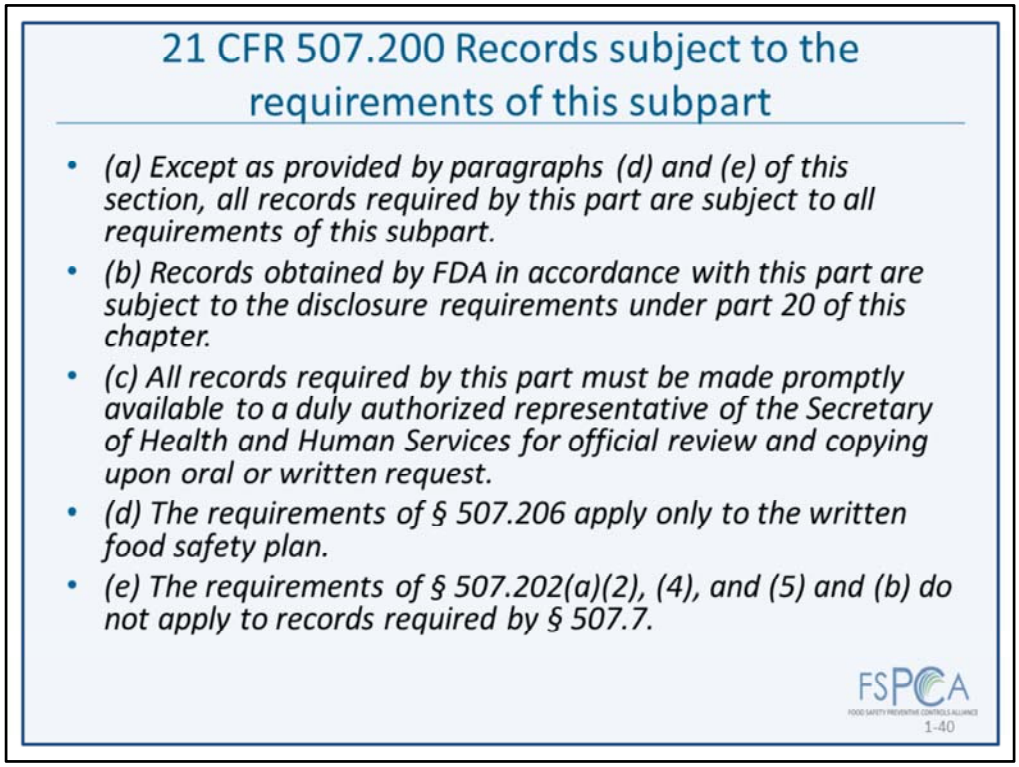
exemption.

Because of the limited application of this subpart, we will not cover in this curriculum. Please refer to appendix 1 for additional information on subpart D.

Subpart E highlights the Supply-Chain Program and its requirements. That subpart will be discussed in depth during Chapter 9.



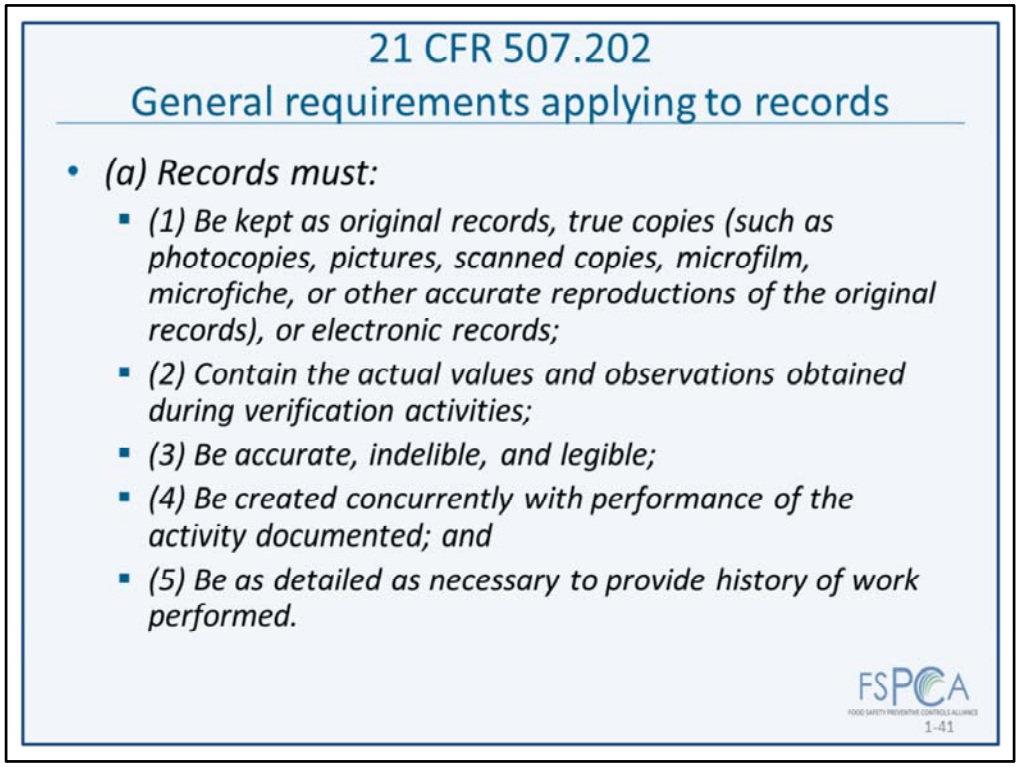
Subpart F is a section that will be referenced often throughout the training. Subpart F provides the requirements applying to records that must be established and maintained to be in compliance with the *Preventive Controls for Animal Food* rule. We will talk about subpart F sections more specifically in the next few slides.



All records that must be maintained are subject to the requirements within the subpart, including those training records for *Qualified Individuals* as previously mentioned at the beginning of Chapter 1. Those records required by Part 507 must be made promptly available for official review and copying upon oral or written request.

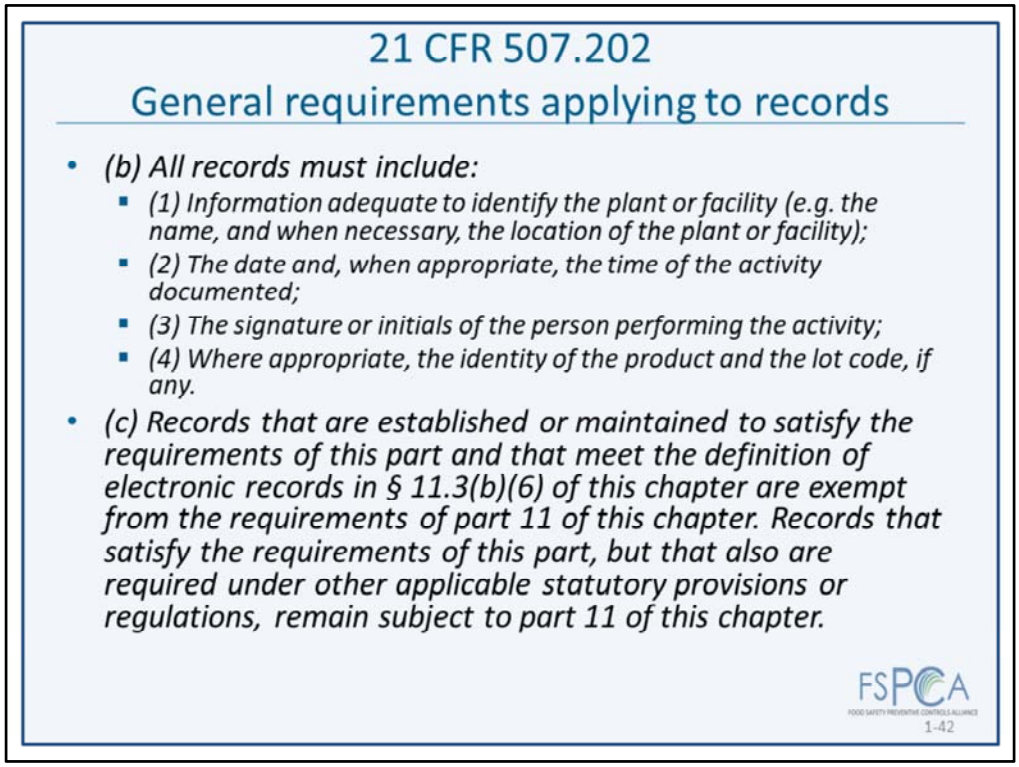
If required records are obtained by FDA (for example, during an inspection or investigation), they are subject to the records disclosure requirements of 21 CFR part 20. (21 CFR 507.200(b)). This means FDA may release them in response to a Freedom of Information Act request, subject to the requirements and exemptions of part 20. Some exemptions that might apply to records subject to this rule protect: trade secrets and confidential commercial or financial information, and information that would constitute a clearly unwarranted invasion of personal privacy of the individuals involved (for example, home addresses and telephone numbers, personal email addresses). FDA may redact or withhold records from a requestor if a record meets these, or other exemptions. For more information about Freedom of Information at FDA, see

http://www.fda.gov/RegulatoryInformation/FOI/ucm390370.htm.



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 electronically. They must contain actual values and observations obtained during monitoring, and, as appropriate, verification activities. They must be accurate, indelible which means they need to be in pen or an electronic form, and legible. The records must be created concurrently with performance of the activity documented and be sufficiently detailed to provide a history of work performed.

As an exception, the records to be established by a *Qualified Facility* do not need to conform to certain requirements, since such requirements are not applicable. As such records established by a *Qualified Facility* do not need to: 1) contain actual values and observations obtained during monitoring, and, as appropriate, verification activities; 2) be created concurrently with performance of the activity documented; or 3) be as detailed as necessary to provide history of work performed.



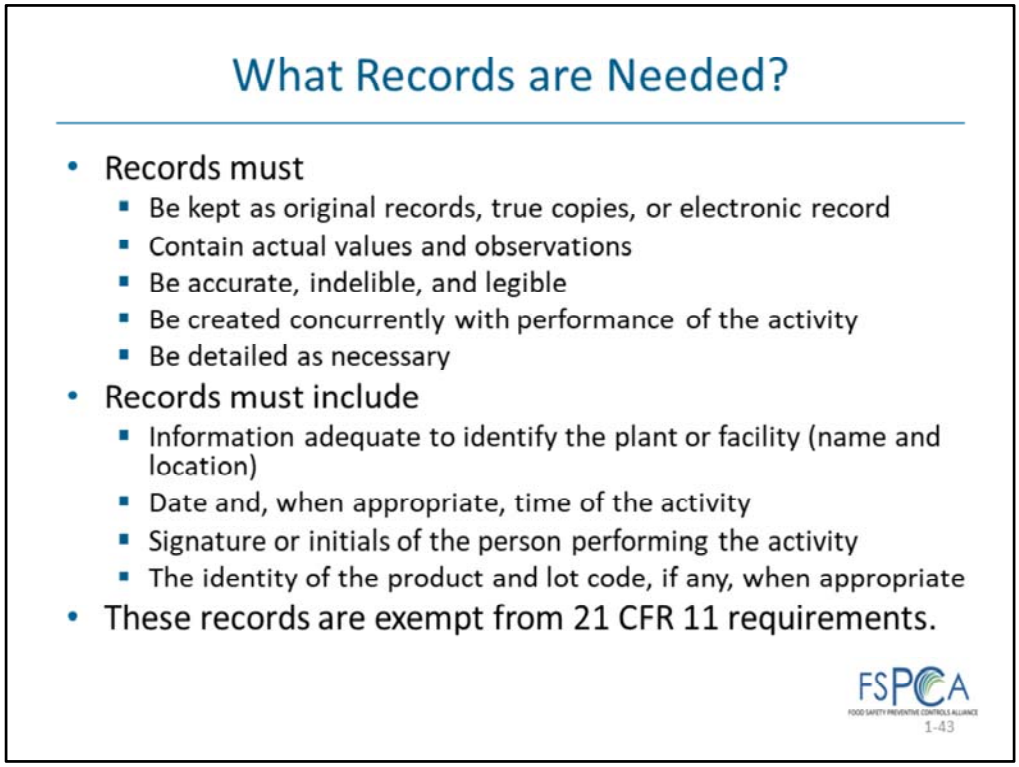
The required records must include:

- Information adequate to identify the plant or facility, including its name and location when necessary.
- They must be dated, and time recorded when appropriate.
- Records must be signed with a signature or initial of the individual performing the activity.
- Where appropriate, the identity of the product or lot code must be included.

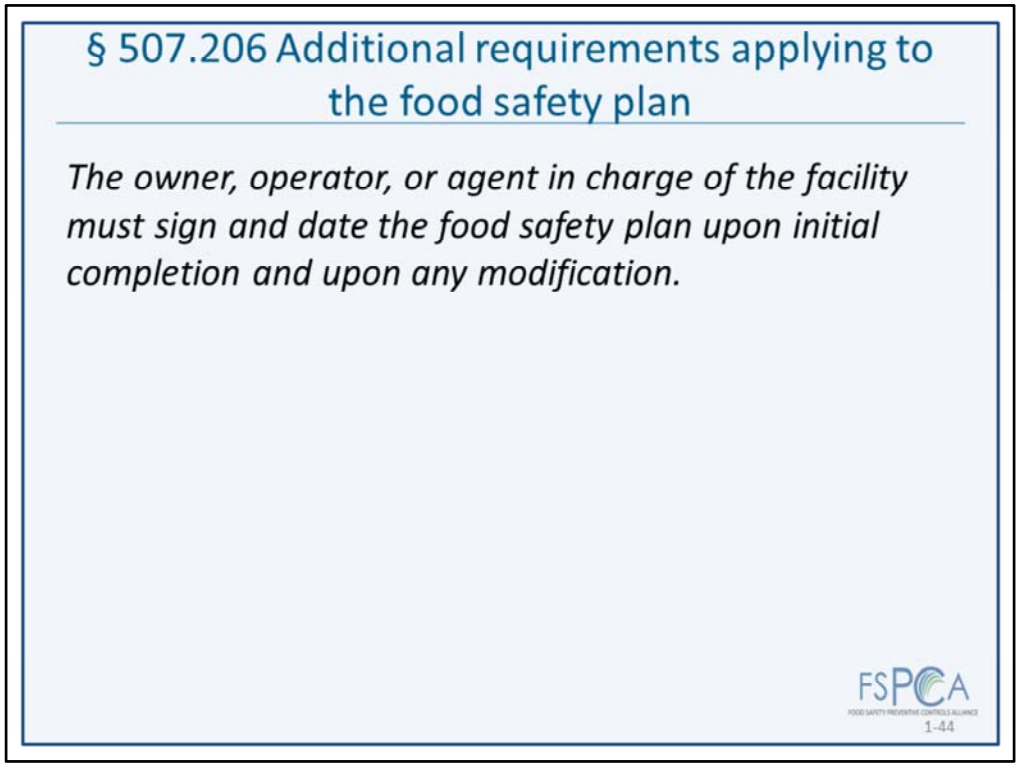
Again, as an exception, the records to be established by a *Qualified Facility* do not need to conform to certain requirements, since such requirements are not applicable. Therefore, records established by a *Qualified Facility* do not need to include the criteria specified on this slide (21 CFR 507.202(b)).

Records required under subpart F are exempt from Title 21 Part 11 requirements, so

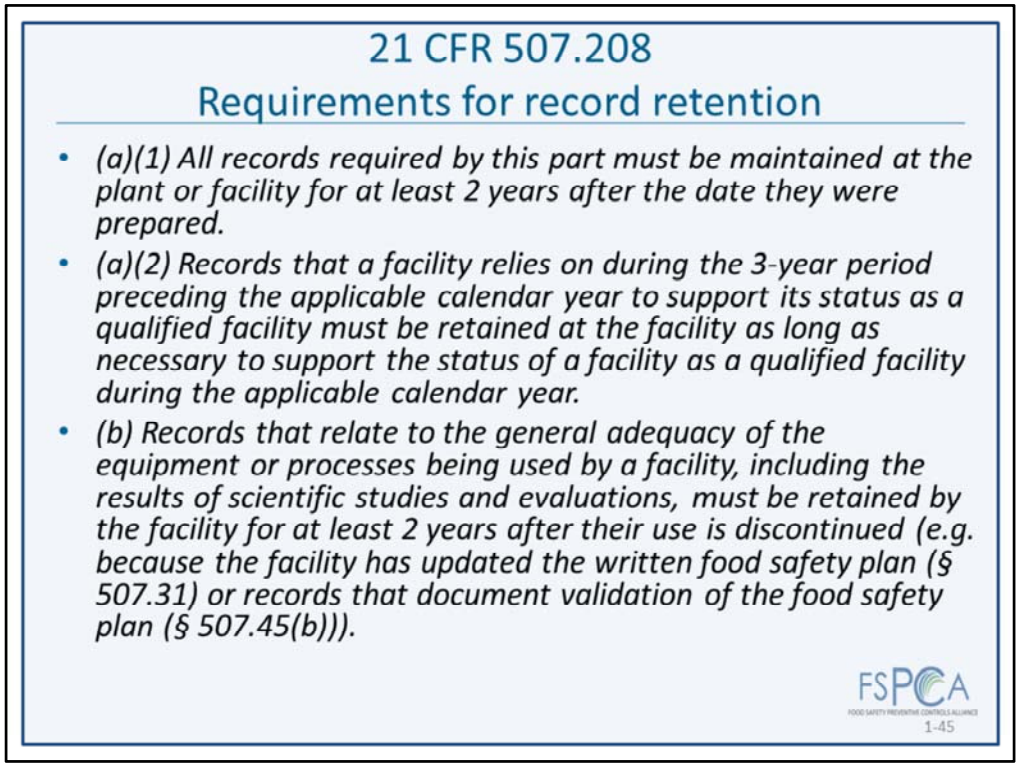
FDA’s requirements for electronic records/electronic signatures do not apply.



Here is a quick summary that may be useful to refer to the requirements of records. Remember, these are the requirements whenever a section designates that records must meet subpart F requirements. Often, this means that current records in the facility may need to be updated to include locations for the facility name and address, as well as date, time, signature, and lot number, where appropriate.

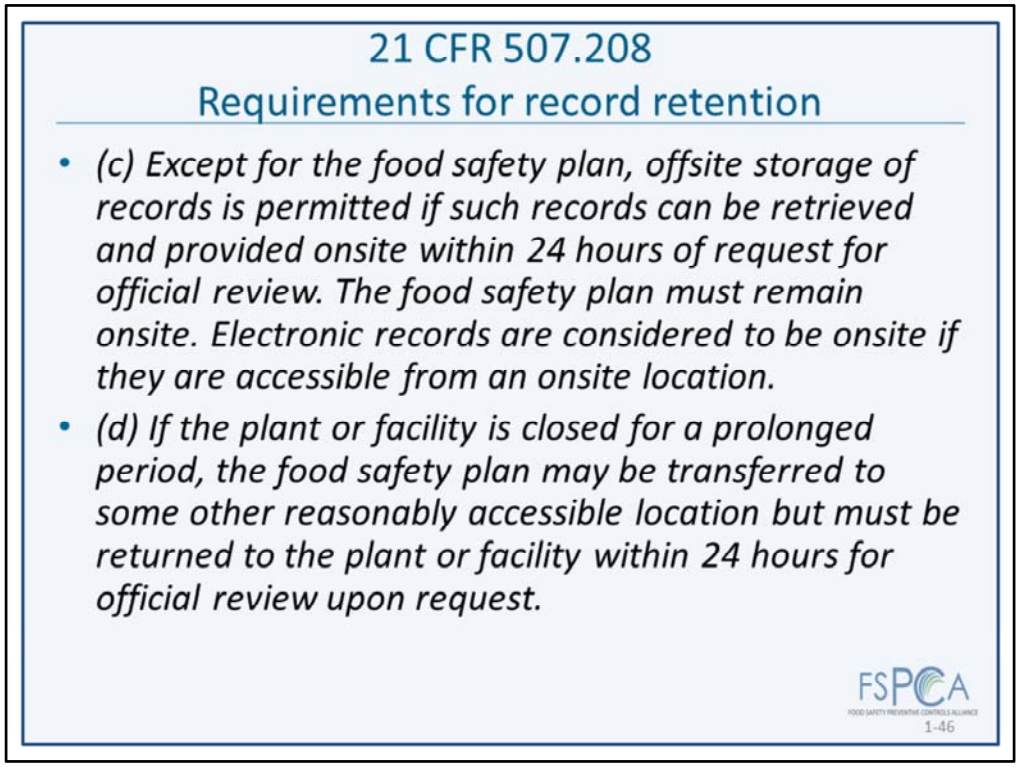


The regulation specifically requires that the food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon the plan's completion and any modification. A preventive controls qualified individual's signature cannot substitute for the owner, operator, or agent in charge. They can be a co-signer of the document, but the requirement specifically states that the food safety plan must be signed by the owner, operator, or agent in charge.

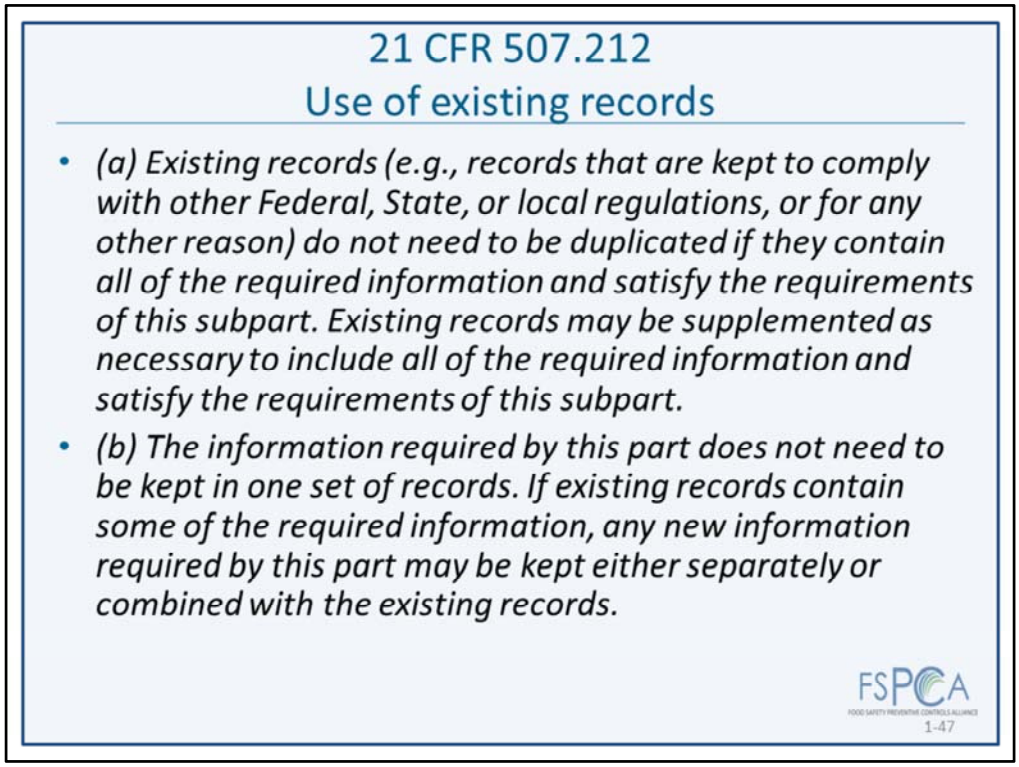


All records must be retained at the animal food facility for at least 2 years after the date they were prepared. Some records may need to be retained even longer, such as 3 years of financial records for *Qualified Facility*, or training records to document the training of *Qualified Individuals* for at least two years after an employee leaves.

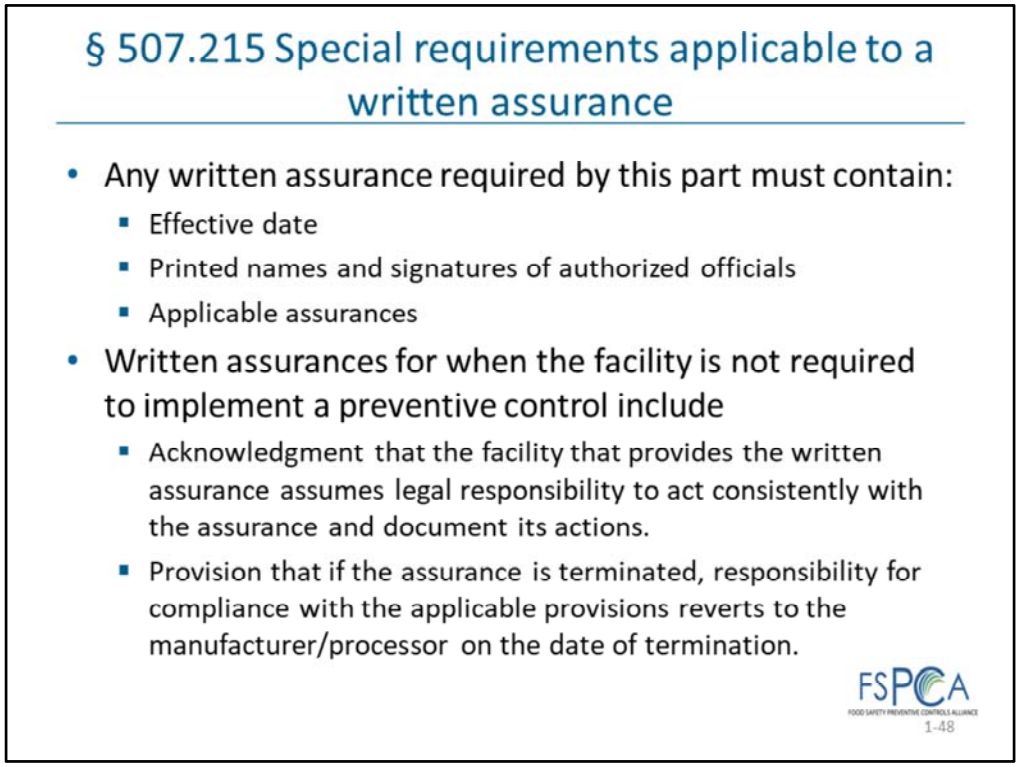
Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued.



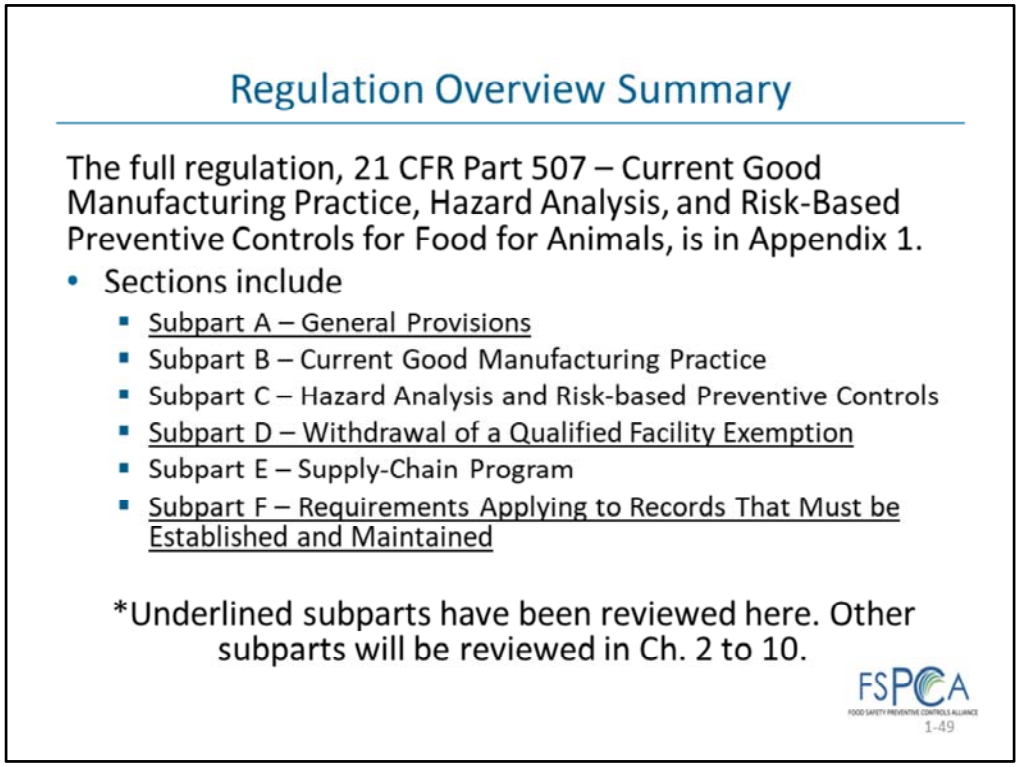
Off-site record storage is permitted if they can be retrieved and provided onsite within 24 hours of request for official review, except that the food safety plans must remain onsite. Electronic records are considered onsite if they are accessible from an onsite location. If the facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request.



Many facilities have existing records that may meet the requirements of 21 CFR 507, and it is acceptable for those records to be used to prevent duplication. These records may need to be supplemented, but the new and existing records may be combined or maintained and stored separately. The rule is flexible as to how the record is documented, as long as the requirements are met.



Finally, any written assurance required by this part must contain the effective date, printed names and signatures of those individuals involved, and applicable assurances. The written assurances for when the facility is not required to implement a preventive control must include acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions and a provision that if the assurance is terminated, responsibility for the compliance with the applicable provisions reverts to the manufacturer or processor on the date of termination.



That ends the heavy regulatory text covered in this chapter. The full regulation can be found in Appendix 1. We have discussed subparts A, D, and F during this chapter. The next chapter will focus on the requirements of subpart B: Current Good Manufacturing Practice requirements.