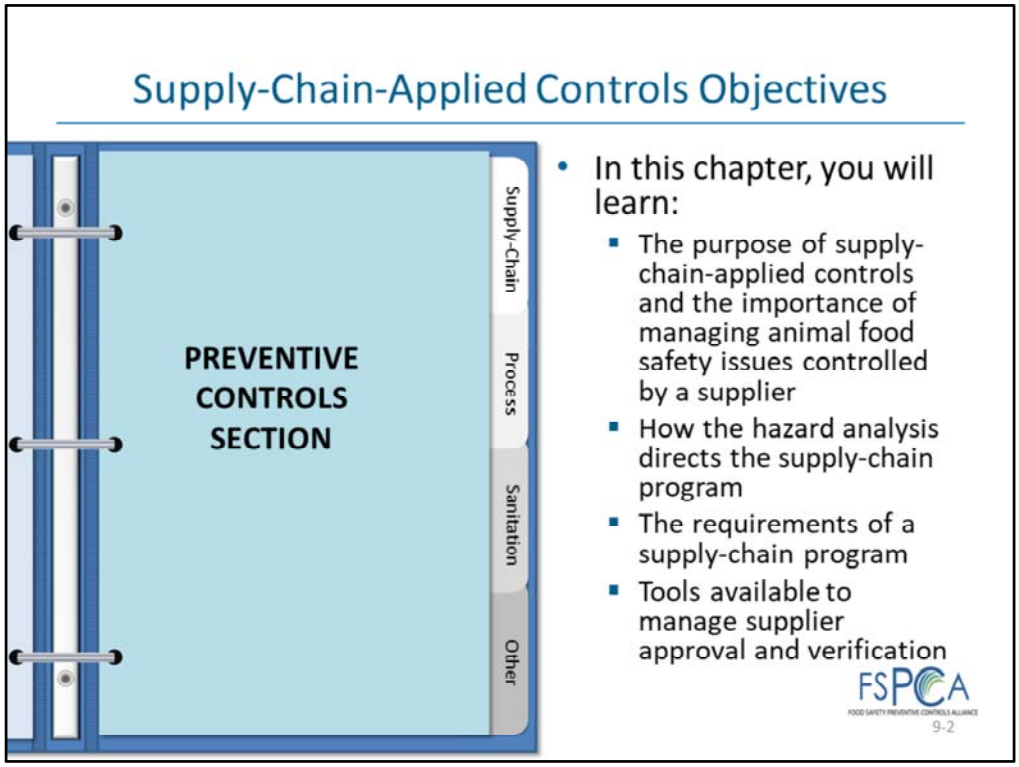
(The supply chain program described in this chapter is not the same as a supply chain program typically thought of by the animal food industry. In fact, supply-chain-applied controls may have limited applicability to animal food. The predominant application of supply-chain-applied controls is expected to be for the control of chemical hazards. Facilities that utilize supply-chain-applied controls must communicate to their supplier the importance of the preventive control since it will be applied by the supplier. In the context of this curriculum, supply-chain-applied controls are the same as supplier controls. The supply chain program is outlined in Subpart E of the Preventive Controls for Animal Food rule.)

The safety of a product depends on much more than just what is controlled within the facility. Known or reasonably foreseeable hazards associated with a raw material or ingredient that a manufacturing facility receives may require a supply-chain-applied control to ensure its safe use. In this chapter, the terms “supply-chain-applied control” and “supply-chain program” refer to requirements in 21 CFR 507 Subpart E – Supply-chain Program in the Preventive Controls for Animal Food rule. Companies may have extensive supplier programs that encompass much more than food safety elements to manage their supplier expectations and performance. This chapter focuses on the requirements of the regulation for verifying measures for control of hazards prior to receipt and not a company’s other supplier efforts.

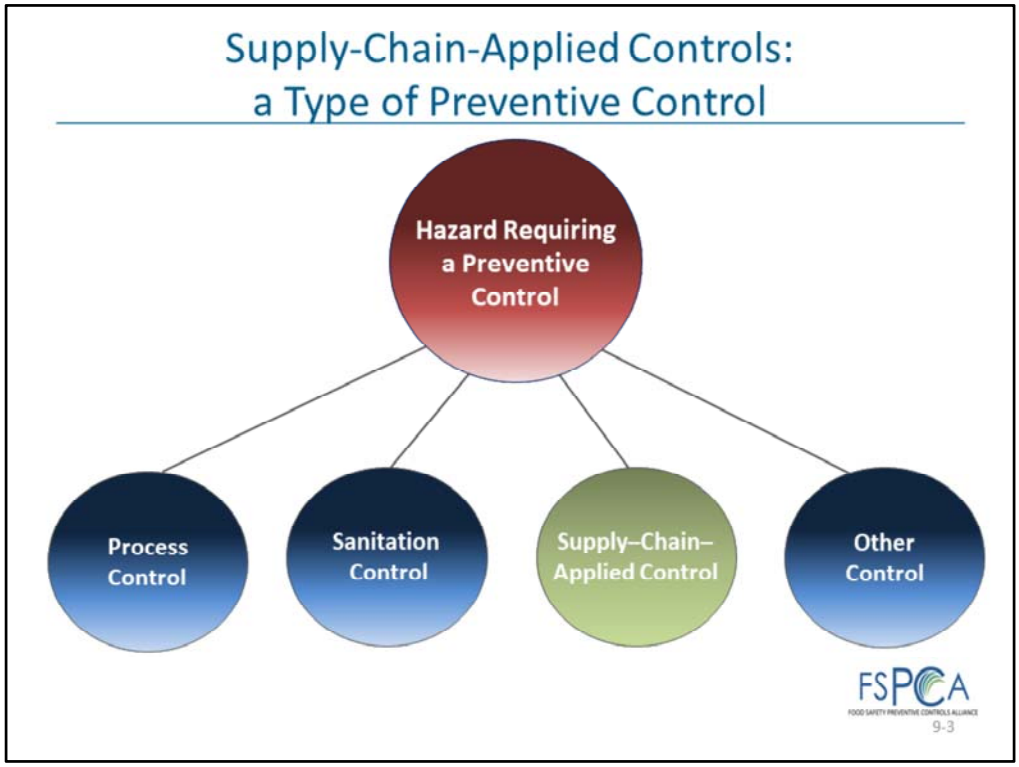


(For simplicity, the term *ingredients* may be used in place of the phrase "raw materials and other ingredients" used in the regulation. If applicable to your operation, see the Foreign Supplier Verification Program requirements on FDA's website.)

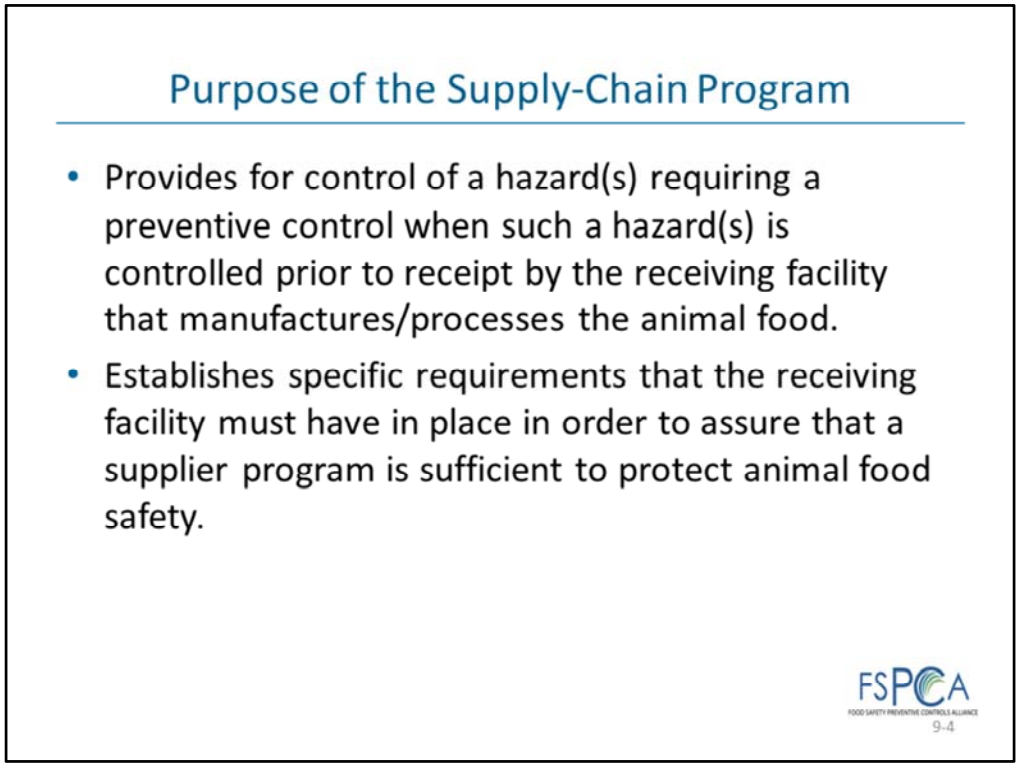
In this chapter, participants will learn the purpose of supply-chain-applied controls, and their role in an animal food safety plan. The results of the hazard analysis determine whether a supply-chain program must be established by a facility. Understanding the potential hazards associated with the supply chain allows a facility to determine whether a preventive control is needed to control those hazards, and whether the preventive control will be applied either within the facility or by the supplier. Required contents for a regulatory compliant supply-chain program are discussed, as well as appropriate activities to verify control at the supplier level. Participants will also learn the record requirements associated with the supply-chain program.

Special requirements for *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* are not covered in this chapter. However, if a facility imports food products or ingredients it will also need to comply with some requirements as described in the FSVP. Regardless of whether ingredients come from a U.S. or a foreign supplier, the principles with respect to food safety are the

same.

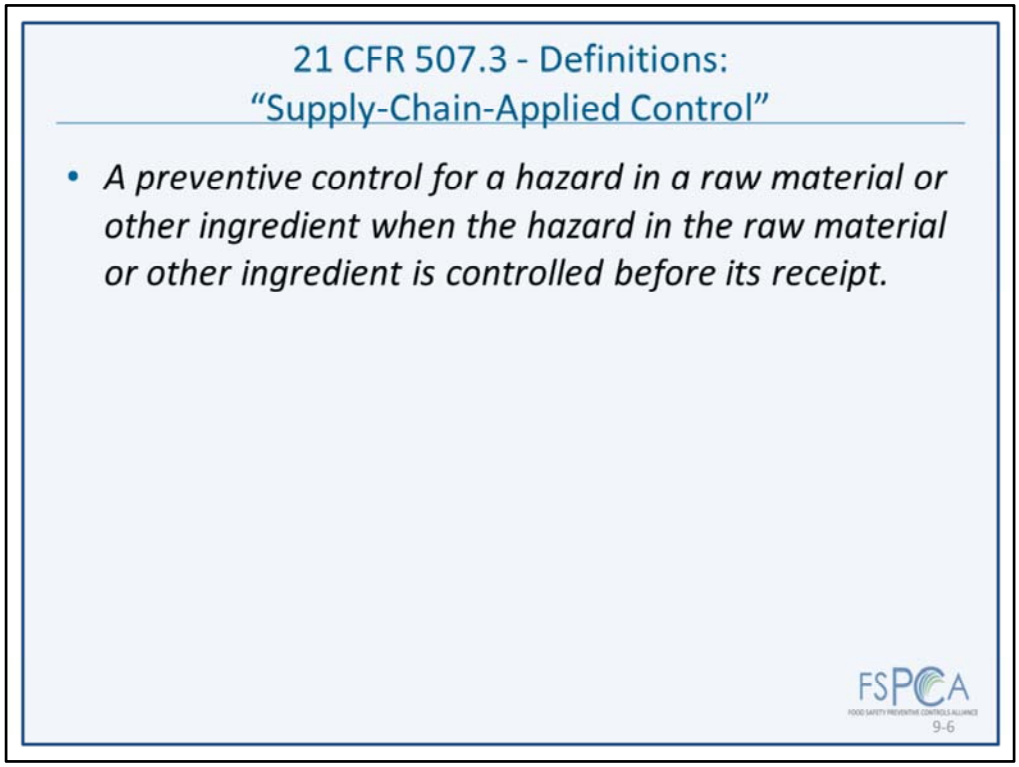


As discussed in Chapter 5, 21 CFR 507.34 introduces the concept of and basic requirements for preventive controls. Recall that a preventive control is required only when the facility has identified a hazard requiring a preventive control. Preventive controls are required to significantly minimize or prevent such hazards. Supply-chain controls are listed as a type of preventive control.

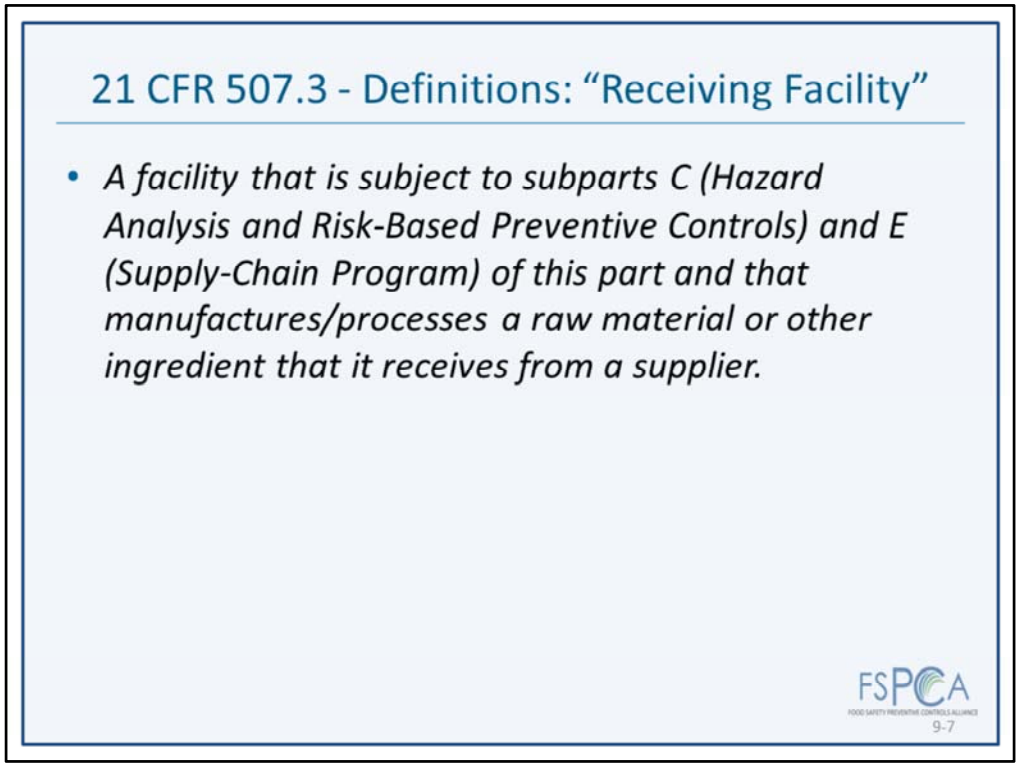


The purpose of the supply-chain program is to provide for the control of a hazard requiring a preventive control prior to receipt by the receiving facility. The supply-chain program establishes specific requirements that must be in place to ensure that the controls are operating as intended. The remainder of this chapter describes how a facility decides if a supply-chain program is warranted, how such a program is to be implemented, and how to assure the program's effectiveness. The ultimate goal of a supply-chain program is to prevent a hazard requiring a preventive control from entering the facility, thus protecting the safety of the animal food.

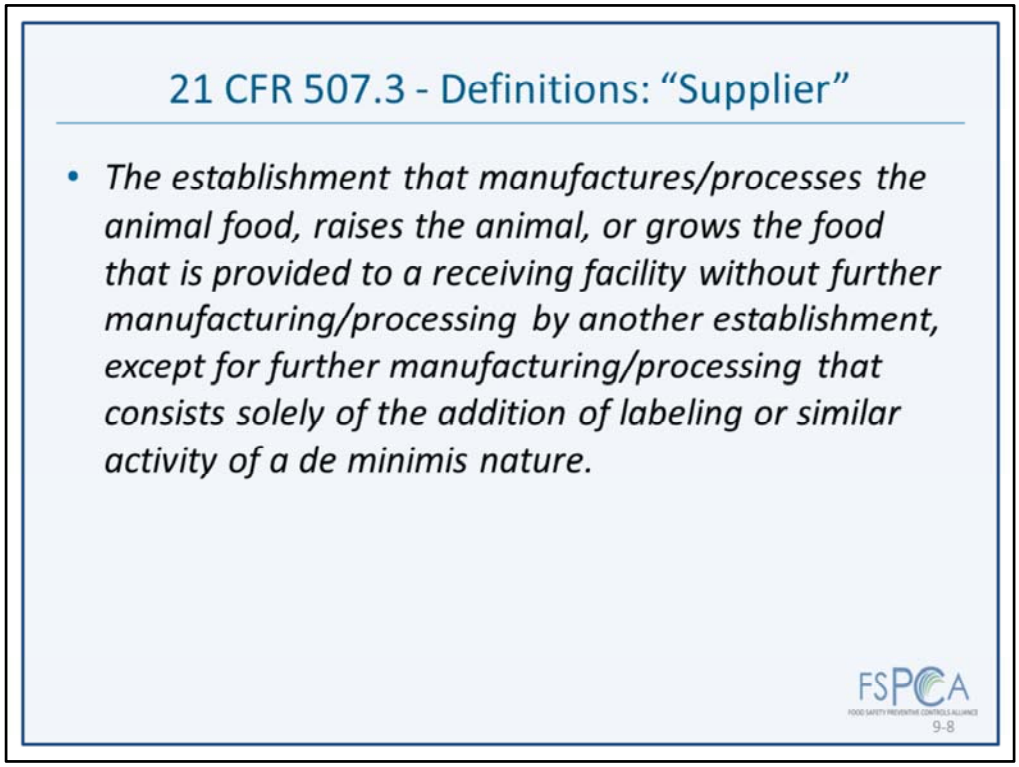
A supply-chain program is a type of preventive control. While the requirements for process and sanitation preventive controls are found in subpart C, the requirements for a supply-chain-applied control are established in a separate subpart. Subpart E, Supply-Chain Program includes eight sections. These sections describe the requirements of a supply-chain program including the responsibilities of the receiving facility, conducting supplier verification activities, and records used to document the program.



There are multiple definitions that are relevant to the supply-chain program. The first of these is "Supply-Chain-Applied Control," which is "*A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt."* The two key items to note in this definition are that this is a type of preventive control, meaning it will need to significantly minimize or prevent a hazard, and that the application of the preventive control occurs before receipt by the receiving facility. This definition, as with all others, is found in 21CFR 507.3, which begins on page 56338 of Appendix I.

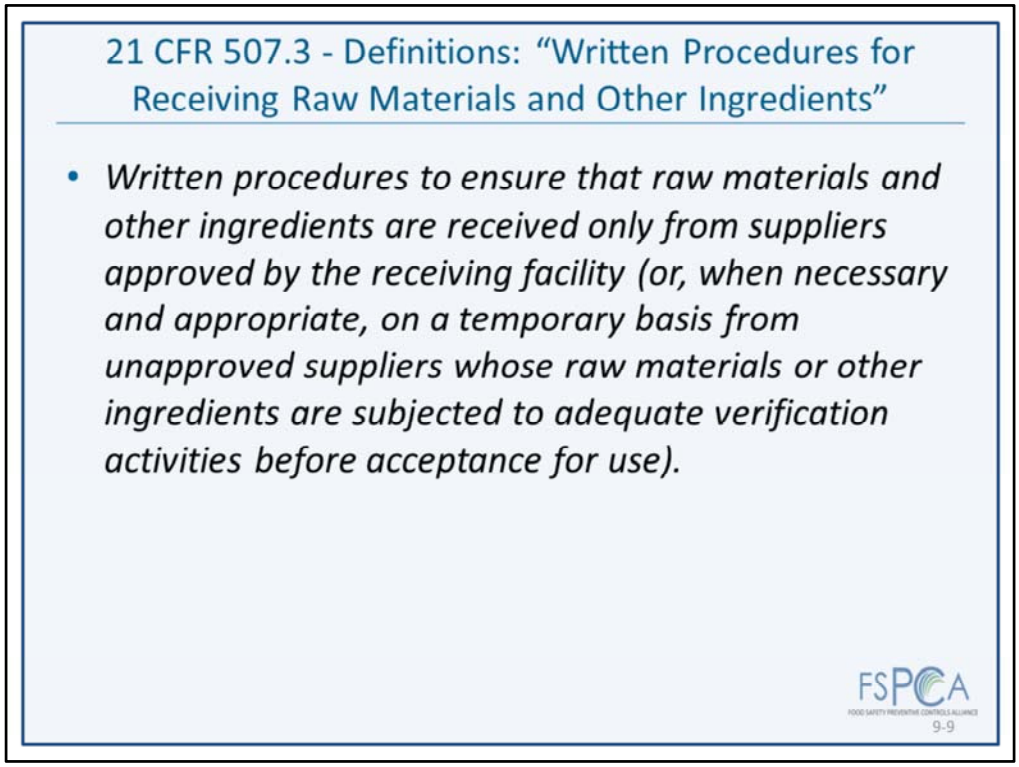


A receiving facility is "*A facility that is subject to subparts C (Hazard Analysis and Risk-Based Preventive Controls) and E (Supply-Chain Program) of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.*" While the *Preventive Controls for Animal Food* rule applies to facilities that manufacture, process, pack, or hold animal food, a receiving facility must be a manufacturer and/or processor.

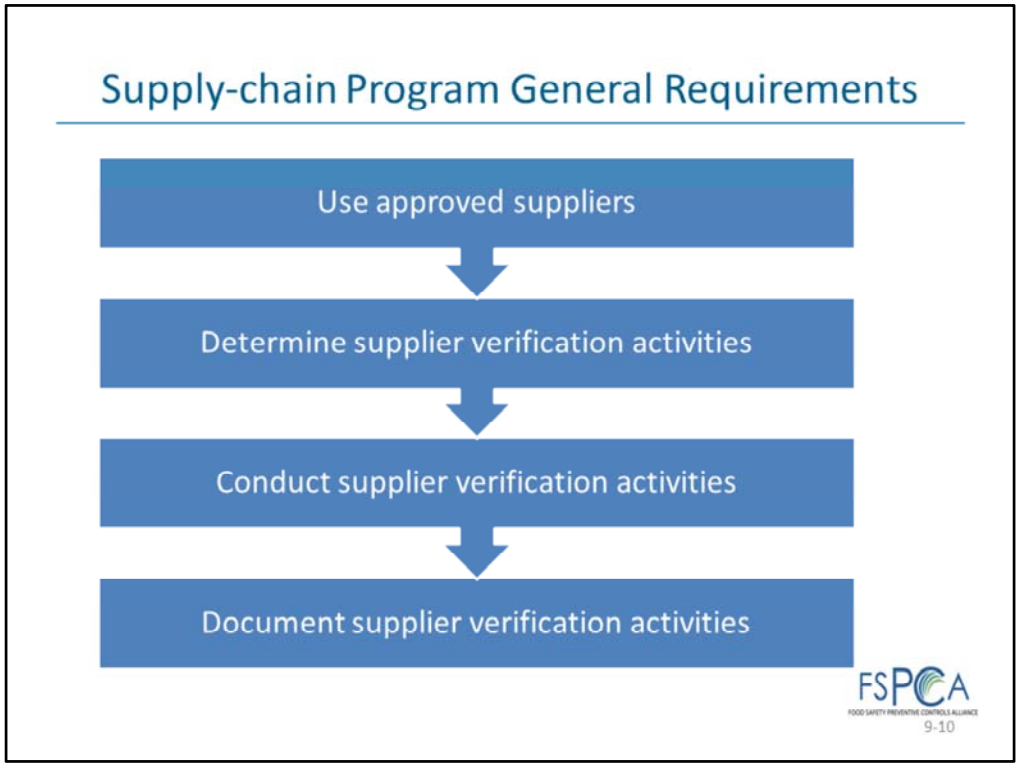


Within the rule, a supplier is defined as "*the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.*"

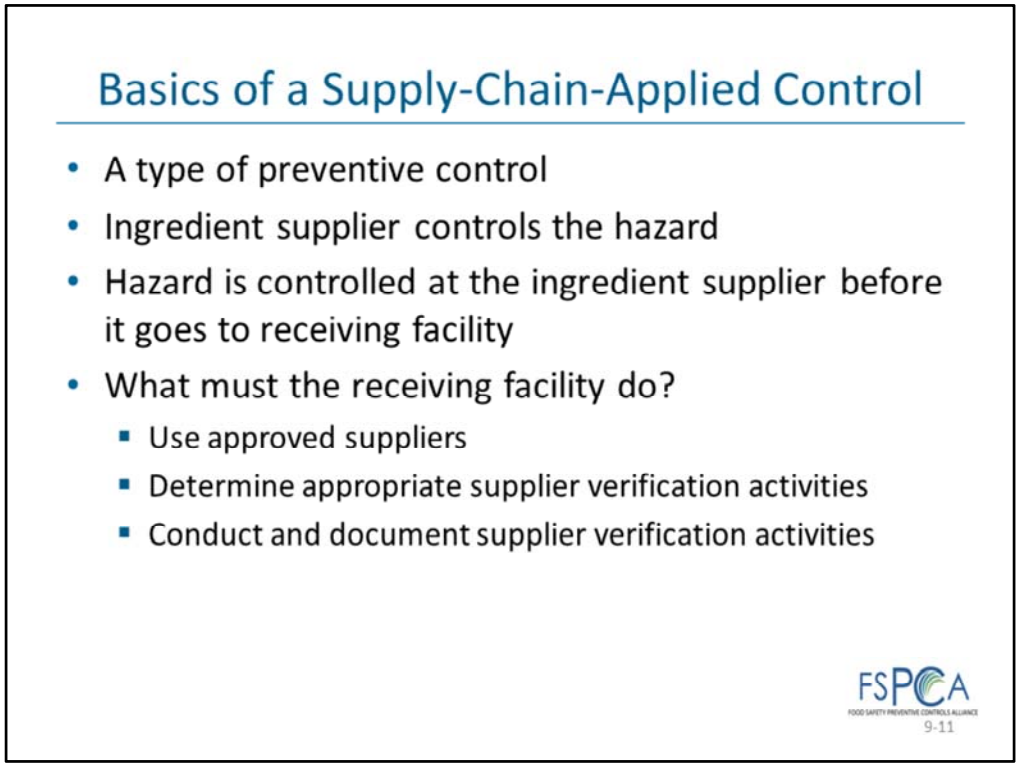
Participants should note that the supplier, by definition, is not necessarily the last establishment in the distribution chain that supplies the ingredient to the receiving facility or the entity that ingredients are purchased from. Rather, the establishment that last performed an activity on the material or ingredient is considered to be the supplier.



In other areas of the curriculum, written procedures are discussed as being necessary to demonstrate that proper actions are taken to protect animal food safety. For the supply-chain program, there is a specific definition for written procedures for receiving raw materials and other ingredients. These are "w*ritten procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).*"



This slide summarizes the general requirements for a supply-chain-applied control. First, the receiving facility must approve supplier for ingredients with a *hazard requiring a preventive control*. Second, the receiving facility must determine appropriate supplier verification activities and conduct those activities. Finally, the supplier verification activities must be documented. These activities will vary, depending on the animal food, the hazard, and the food safety system. Examples may include onsite audits, sampling and testing of ingredients, and/or a review of relevant food safety records.

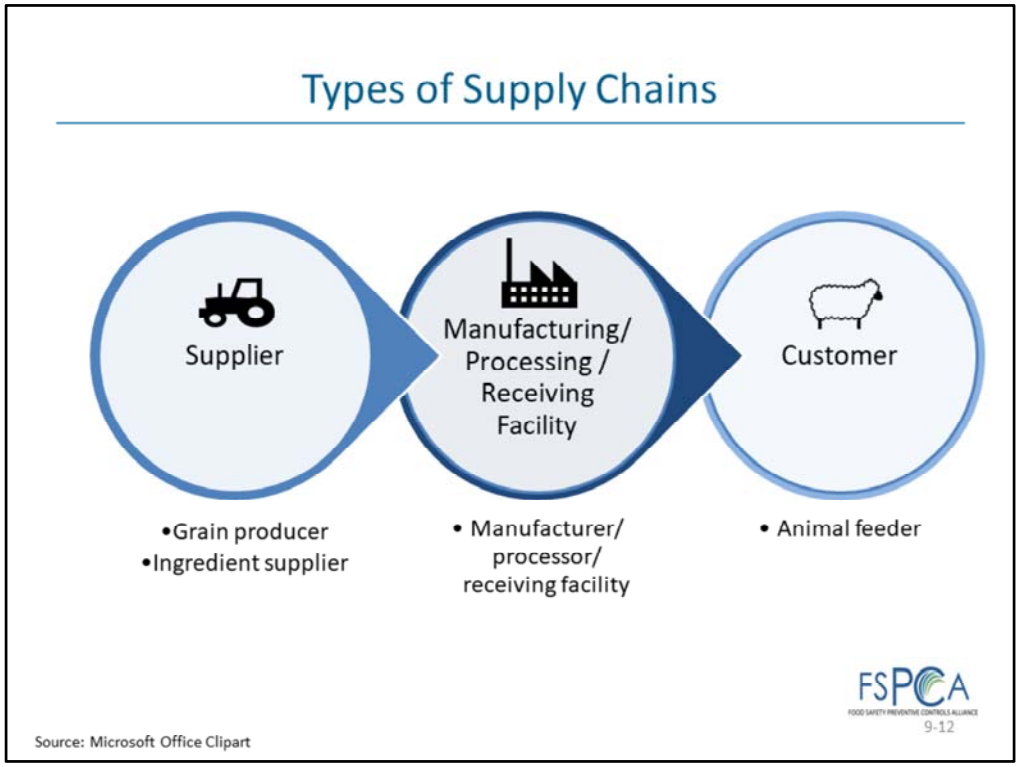


If a facility conducts a hazard analysis and determines that one of its raw materials or other ingredients has a hazard requiring a preventive control AND the hazard needs to be controlled before it is received – that is when the facility would establish a supply-chain-applied control.

Under the supply-chain program – the hazard is controlled by the supplier of the raw material or other ingredient before it goes to the receiving facility.
Some of the requirements for the receiving facility under the supply-chain program include:

- Using only approved suppliers
- Determine the appropriate supplier verification activities
- Conducting and documenting supplier verification activities

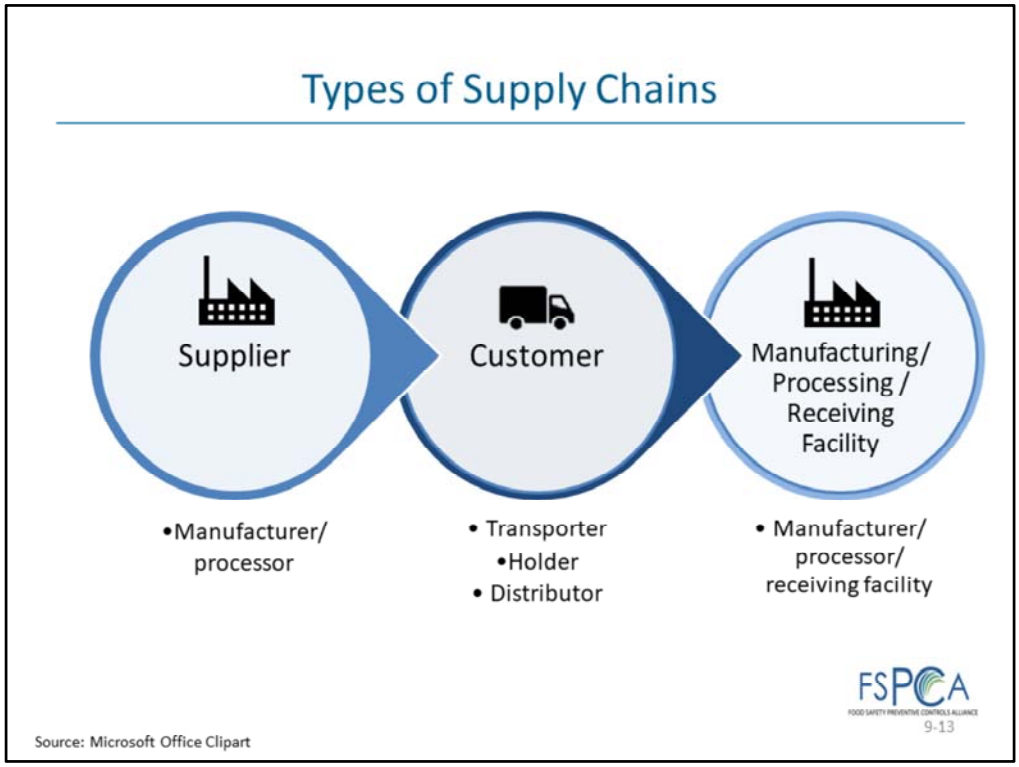
These requirements will be covered throughout the remainder of this chapter.



To understand the requirements of the supply-chain program, it is important to understand the definitions of supplier, receiving facility, and customer and the relationship between these entities in the context of the regulation.

The example shown here is the most recognized version of a supply chain, with an ingredient supplier, a manufacturer, and an animal feeder as the customer. In this case, the manufacturer/processor is the "receiving facility" for a raw material or other ingredient. A "supplier" may be a manufacturer or processor of the material or ingredient received. Note that for incoming raw agricultural commodities (such as corn, oats, or soybeans), the "supplier" is the entity that grows the food (farmer), if no further processing of the ingredient occurs. An entity holding or transporting the ingredient is not the supplier unless some processing activity occurs while the ingredient is in their possession. It is also important to keep in mind that farms and facilities engaged in holding (such as some grain elevators) of raw agricultural commodities may be exempt from the *Preventive Controls for Animal Food* rule.

The receiving facility must document and implement a supply-chain program if a hazard requiring a supply-chain-applied control is identified through the hazard analysis.

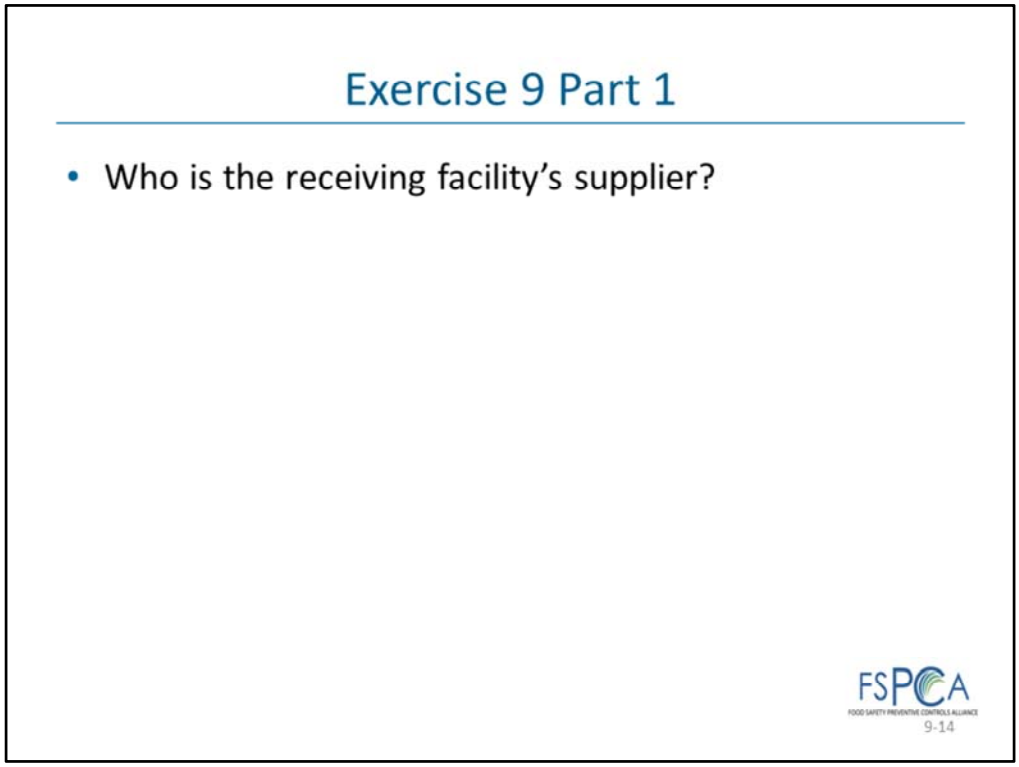


Some versions of the supply chain may be less recognizable.

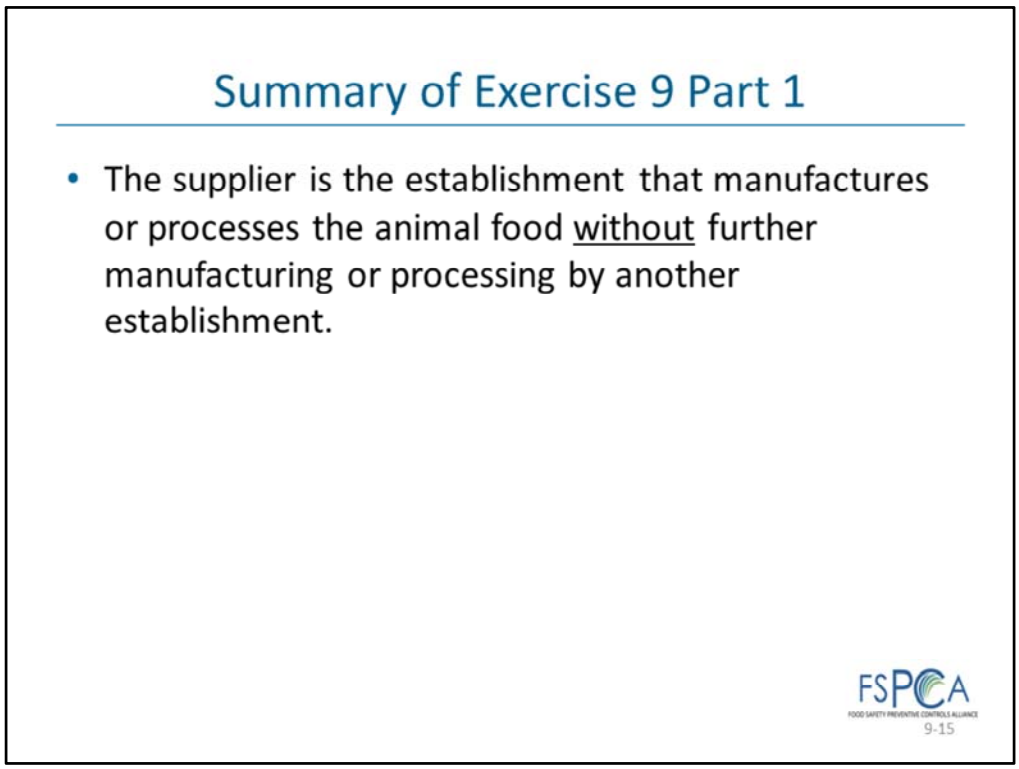
Consider that the "customer" is an entity that purchases the product. A customer may be a transporter or holding facility, an animal feeder, or another manufacturer/processor. However if a facility distributes to another receiving facility in the supply chain, the facility may be considered to be a supplier.

For example, a manufacturing facility (Facility A – 1st circle) may take in raw ingredients and process them into a premix, supplement, or some other intermediate product that will not be fed directly. Facility A's customer (2nd circle) could be a distributor who will sell the ingredient to Facility B (the receiving facility – 3rd circle), which uses the product to manufacture/process finished food. Although the product is not sold directly to Facility B, Facility A may be considered the supplier since it was the last entity to manufacture/process the product.

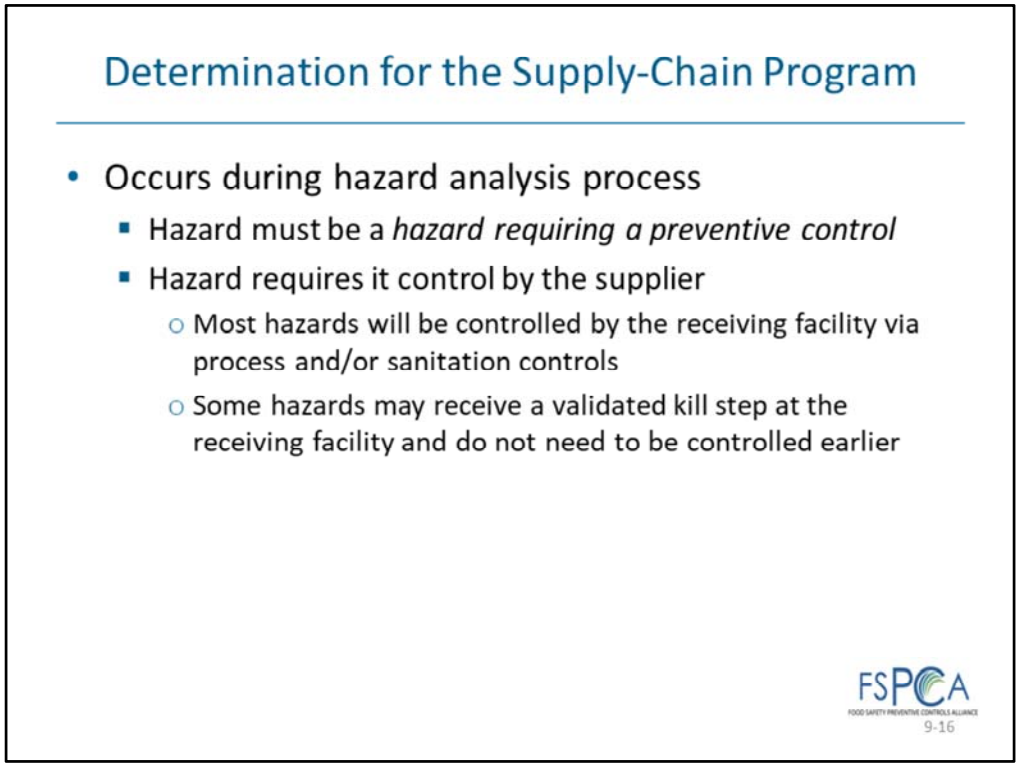
With this in mind, facilities should consider where they may exist in the supply chain, and whether they are a supplier, receiving facility, or potentially both.



Exercise Part 1. This activity will help participants determine who are considered suppliers to a receiving facility. This is important for determining which facilities the receiving facility must approve as suppliers and conduct supplier verification activities.



The supplier is the establishment that manufactures or processes the animal food without further manufacturing or processing by another establishment.

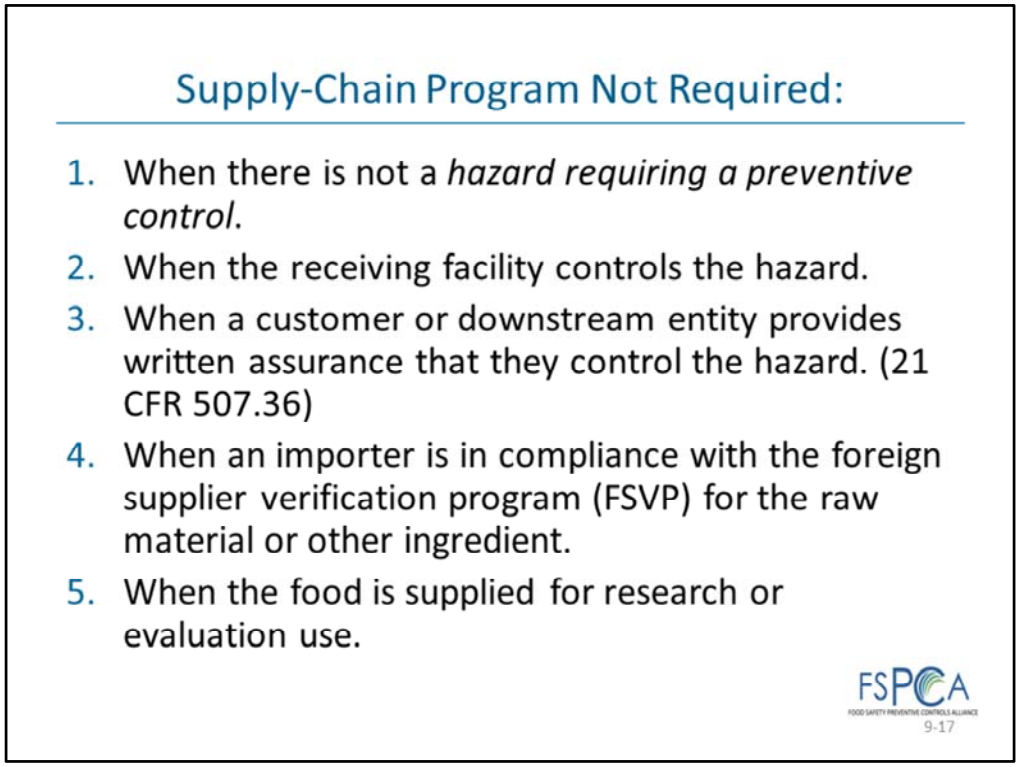


During the hazard analysis and preventive controls identification process, the facility should consider whether a supply-chain applied control is best suited to control a hazard requiring a preventive control. A supply-chain applied control is necessary when the supplier is expected to control the hazard requiring a preventive control. Supply-chain applied controls are typically used in situations where a hazard requiring a preventive control may be present in an incoming material or raw ingredient and the facility will not be using another type of preventive control to control the hazard itself.

It is important to note that a hazard originating from a supplier does not necessarily have to be controlled by a supply-chain applied control. Rather, the hazard analysis process determines when a hazard requiring a supply-chain-applied control exists. The outcome of the hazard analysis may indicate that the received ingredients do not have hazards requiring a preventive control, and therefore the ingredients are not subject to a supply-chain-applied control.

The hazard analysis may indicate that an ingredient and its supplier do have an association with a specific food safety hazard but the manufacturer doesn't establish a supply-chain applied control. In this case, a supply-chain program would not be required if a preventive control for the hazard is implemented within the facility. For example, if a pathogen that is associated with an ingredient is

controlled by implementing a validated kill step, the facility does not need a supply-chain program.



(Items #1 and #2 on this list are most commonly the reasoning for facilities to not have a supply-chain applied control.
In order to meet #5, the following must occur:

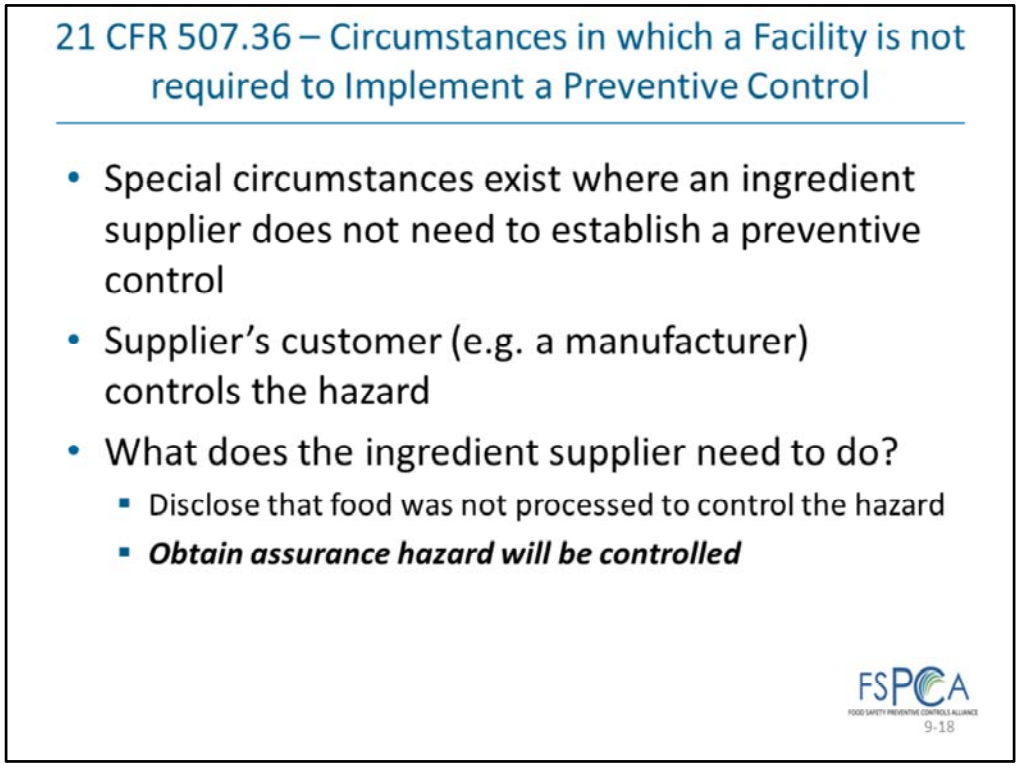
- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled "Food for research or evaluation use-"
- The food is supplied in a small quantity consistent with a research, analysis or quality assurance purpose, it is used only for that purpose and unused food is properly disposed of; and
- The food is accompanied with documents stating that it will be used for research or evaluation and cannot be sold or distributed to the public.)

A supply-chain program is not required in the following situations:

1. The hazard analysis concludes that there are no hazards requiring a supply-chain-applied control,
2. The receiving facility controls the hazards requiring a preventive control within the facility,
3. When a customer or downstream entity provides written assurance that they control the hazard (would also apply to the potential application of other preventive control categories),
4. When an importer of the raw material or other ingredient and are in compliance with the FSVP (if in compliance with FSVP, the facility will have documentation

that provides assurance the hazard(s) requiring a supply-chain applied control have been significantly minimized or prevented), or

5. The animal food is supplied for research or evaluation use (for example, if an animal food is produced solely for the purpose of evaluating the effectiveness of a new product on animal performance).



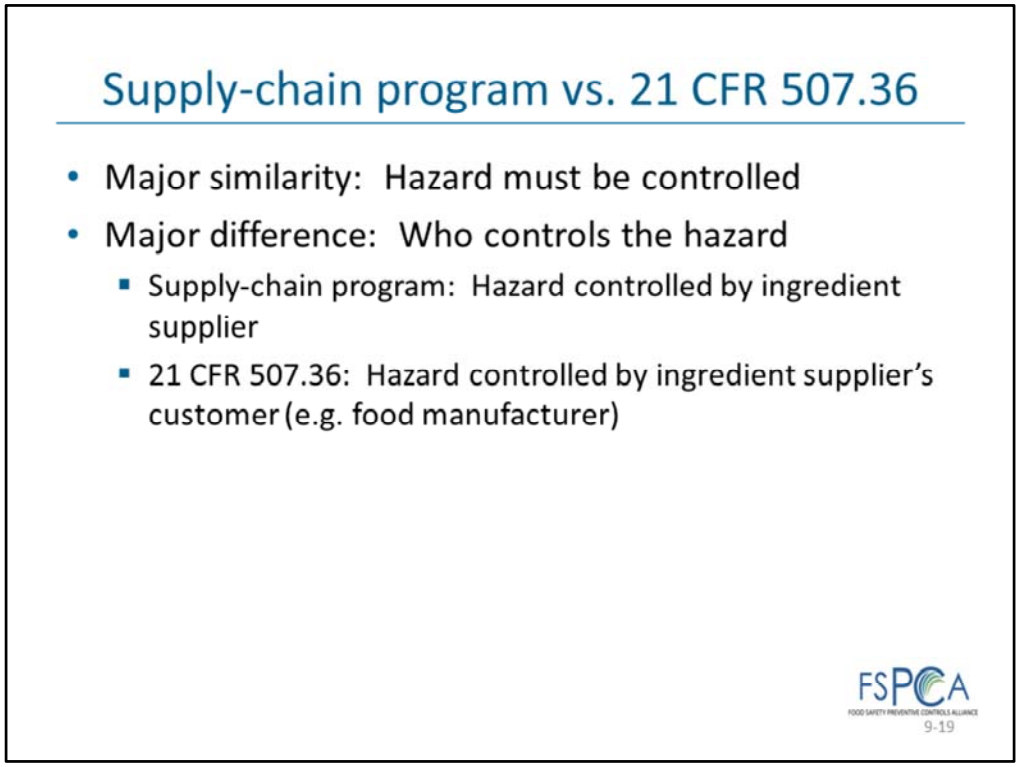
(This slide applies to all Subpart C, not just to the supply-chain program. An example application of 507.36 would be a supplier of animal by-product meal requiring assurance from its customer (an extruded pet food company) that preventive controls will be implemented to control *Salmonella*. In this case, the supplier of the protein meal may manufacture and ship knowingly contaminated product because it has an intended downstream commercial heat step.)

The situation described in this slide is the opposite of a supply-chain-applied control as the responsibility for controlling the hazard is placed on the customer. 21 CFR 507.36 provides circumstances that allow a manufacturer/processor to not implement a preventive control. In these cases, the supplier is not required to implement a preventive control because the preventive control is going to be applied further in the supply chain (e.g. by the customer, who is also a manufacturer/processor.)

The supplier does have the following responsibilities under the regulation:
• The facility discloses in documents accompanying the animal food that the animal food is "not processed to control [identified hazard]," and
• The facility obtains written assurance that the customer has established and is following procedures (identified in the written assurance) that they will significantly minimize or prevent the identified hazard.

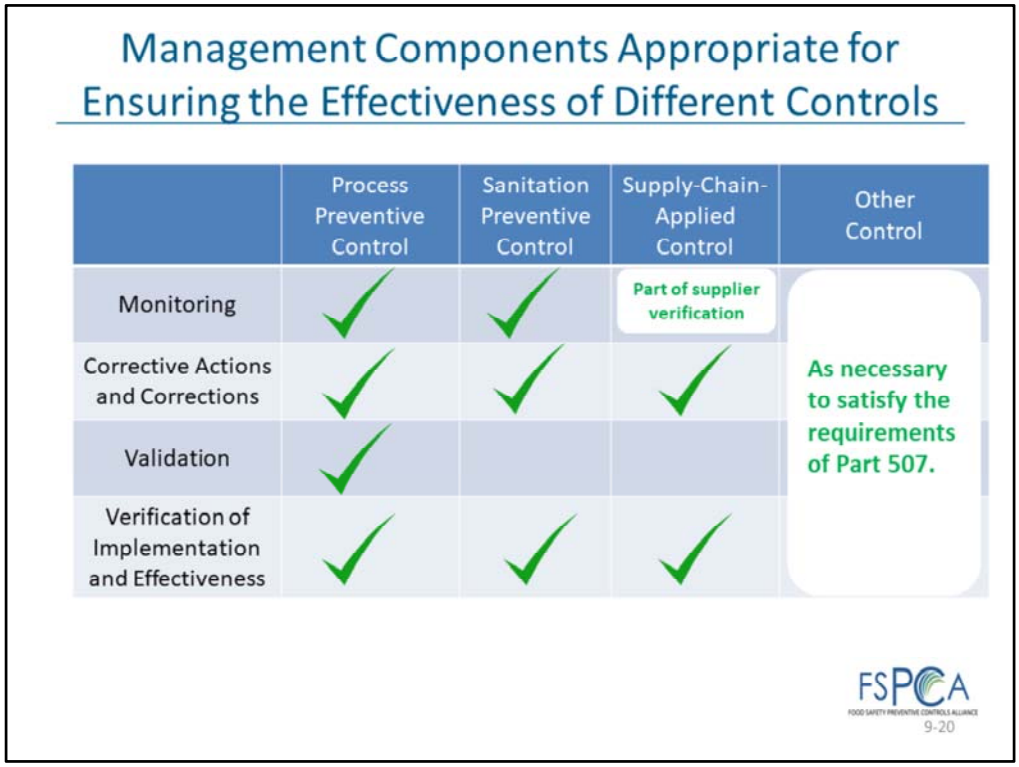
The written assurance is necessary to verify that the customer is taking on the responsibility for control of the hazard and has established and is following procedures to significantly minimize or prevent the hazard.

The supplier must retain the documented written assurance in accordance with subpart F. And the customer is required (under 21 CFR 507.37) to act consistently with assurance, including documenting actions taken to satisfy the written assurance.



To summarize the previous slide, 21 CFR 507.36 applies to any hazard requiring a preventive control. If the customer verifies that appropriate steps will be taken to control the hazard, the supplier is not responsible for implementing a preventive control.

While this circumstance may apply to any preventive control type, it seems to fit most appropriately in the discussion of supply-chain-applied controls. The common thread is that the hazard must be controlled. The difference is in who implements the control, and which specific recordkeeping requirements apply.



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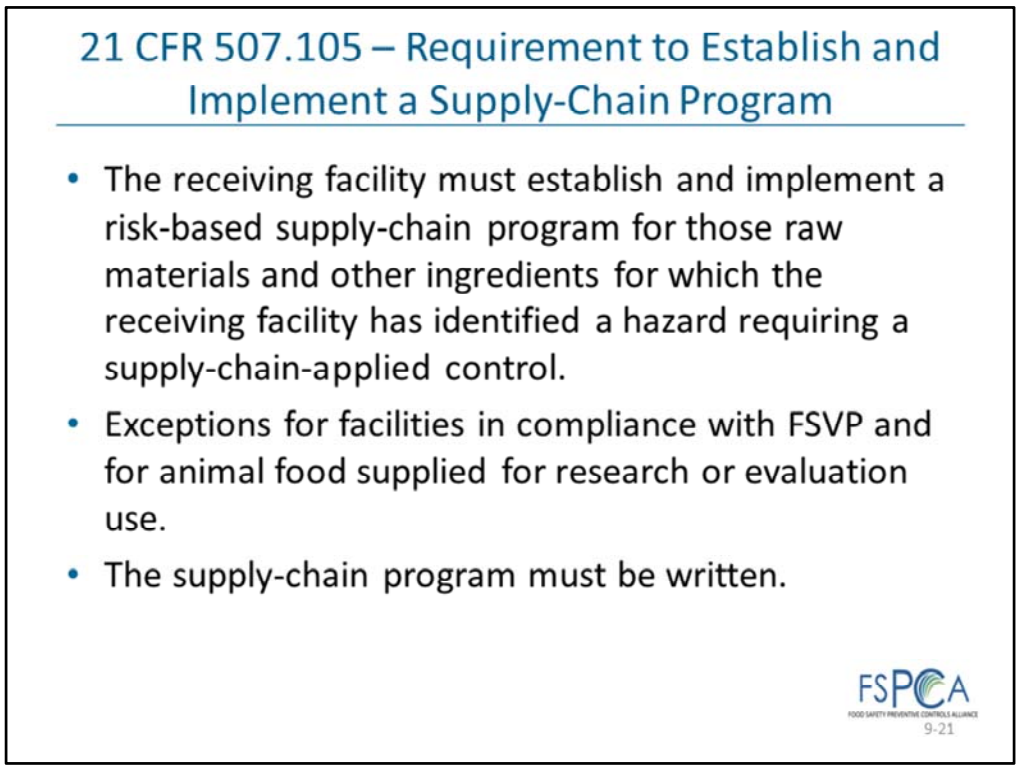
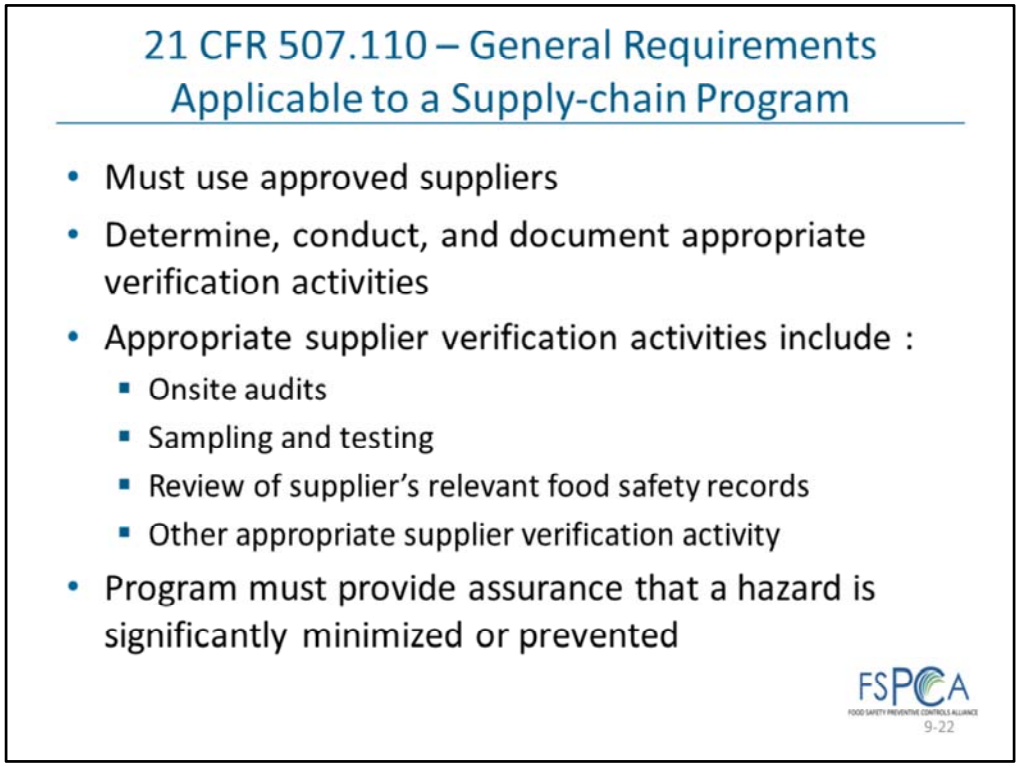


(21 CFR 507.105(c) provides requirements for a situation in which a facility has to conduct supplier verification on its supplier and an additional entity because both entities may apply controls for a hazard. The only currently known example of this situation is fresh produce. Current application in animal food is unknown. This requirement is expected to have limited applicability for animal food and is not covered in this curriculum.)

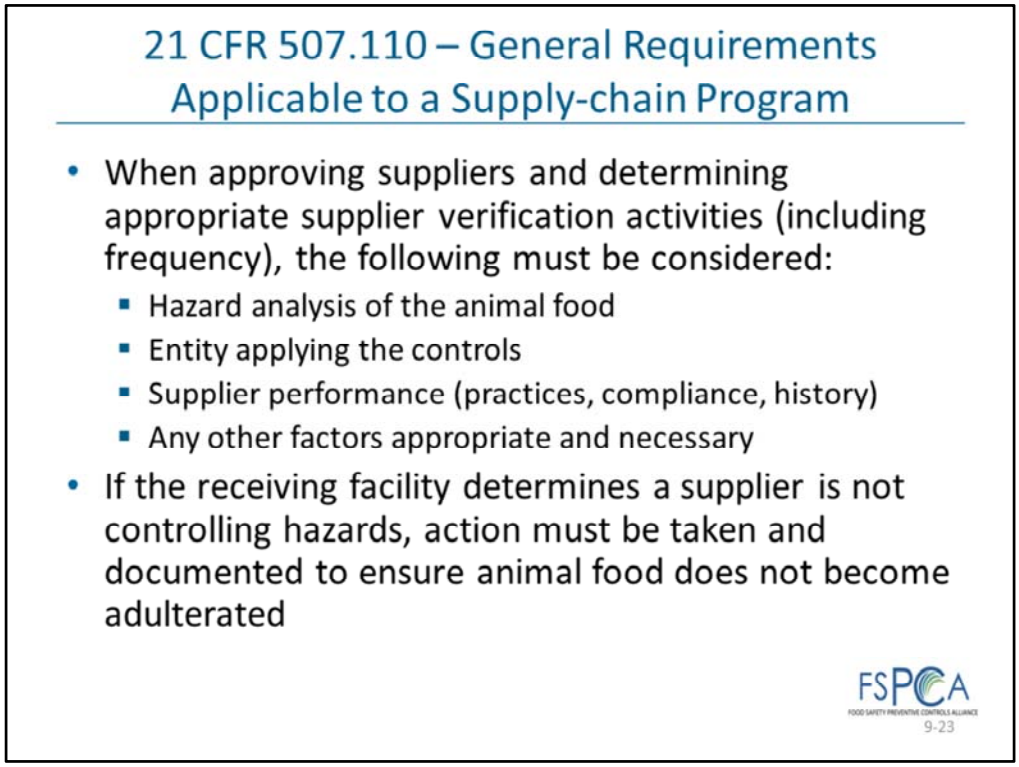
21 CFR 507.105 describes the requirement to establish and implement a supply-chain program. A facility must establish and implement a supply-chain program when it identifies a hazard requiring a preventive control and it selects a supply-chain-applied control. The need for a supply-chain applied control is determined through the hazard analysis process, and therefore the need for such a control is risk-based and dependent on the materials and ingredients being received by a facility. As described in the previous slide, there are exceptions, such as when the facility is the importer of the ingredient and the facility is in compliance with FSVP requirements. In addition, the supply-chain programs do not apply to animal food supplied for research or evaluation use. As with other preventive controls, the supply-chain program must be written.



(In most cases, brokers and distributors are not suppliers as defined in this rule. Thus, they cannot approve suppliers – that is an activity only the receiving facility can conduct.)

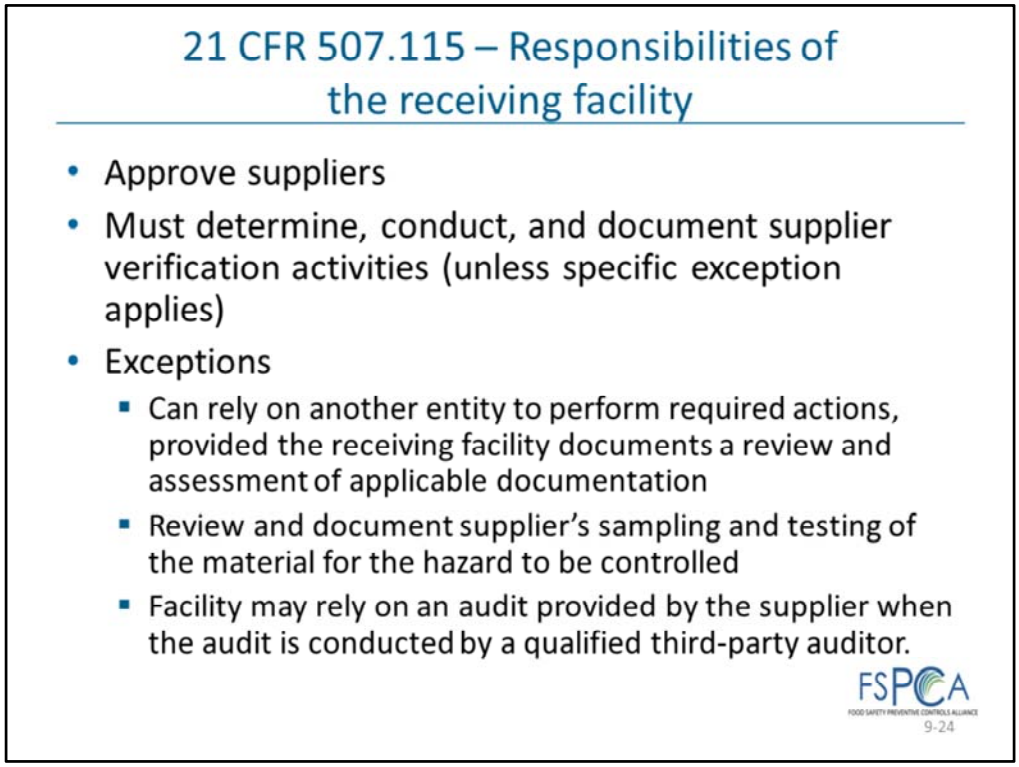
21 CFR 507.110 provides the general requirements that are applicable to a supply-chain program. When a supply-chain program is required, the receiving facility must use approved suppliers. While flexibility is given for "who" can complete other components of the supply-chain program, only the receiving facility can approve suppliers.
The facility must determine, conduct, and document appropriate supplier verification activities. These activities may include onsite audits, sampling and testing, and/or a review of relevant food safety records. There may also be other appropriate supplier verification activities, which could be based on the supplier's performance and the risk associated with the raw material or other ingredient.

As with all preventive controls, the supply-chain program must provide assurance the hazard being controlled is significantly minimized or prevented.



The rule lays out specific considerations that must be taken into account when approving suppliers and determining appropriate verification activities (including frequency). The receiving facility must consider the results of the hazard analysis, which gives an indication of the risk posed by the hazard. The receiving facility must consider the specific entity applying the controls, as well as the entity's performance. Factors associated with supplier performance that must be considered include:

- Procedures, processes, and practices related to food safety,
- Compliance with applicable FDA food safety regulations, and
- Food safety history. If the receiving facility determines that a supplier is not controlling a hazard in accordance with the supply-chain program, corrective actions must be taken and documented to ensure that ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated.



(The facility may **not** accept any of the following as a supplier verification activity:

1. A determination by its supplier of the appropriate supplier verification activities for that supplier;
2. An audit conducted by its own supplier;
3. A review by its supplier of that supplier's own relevant food safety records; or
4. The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of 21 CFR 507.110(b)(4).)

It is the responsibility of the receiving facility to approve suppliers. While supplier verification activities and other pieces of the program can be conducted by other entities, only the receiving facility can approve suppliers under the regulation.

With some specific exceptions, the receiving facility is responsible for determining, conducting, and documenting the supplier verification activities, including a determination of the frequency that the verification activities need to be conducted.

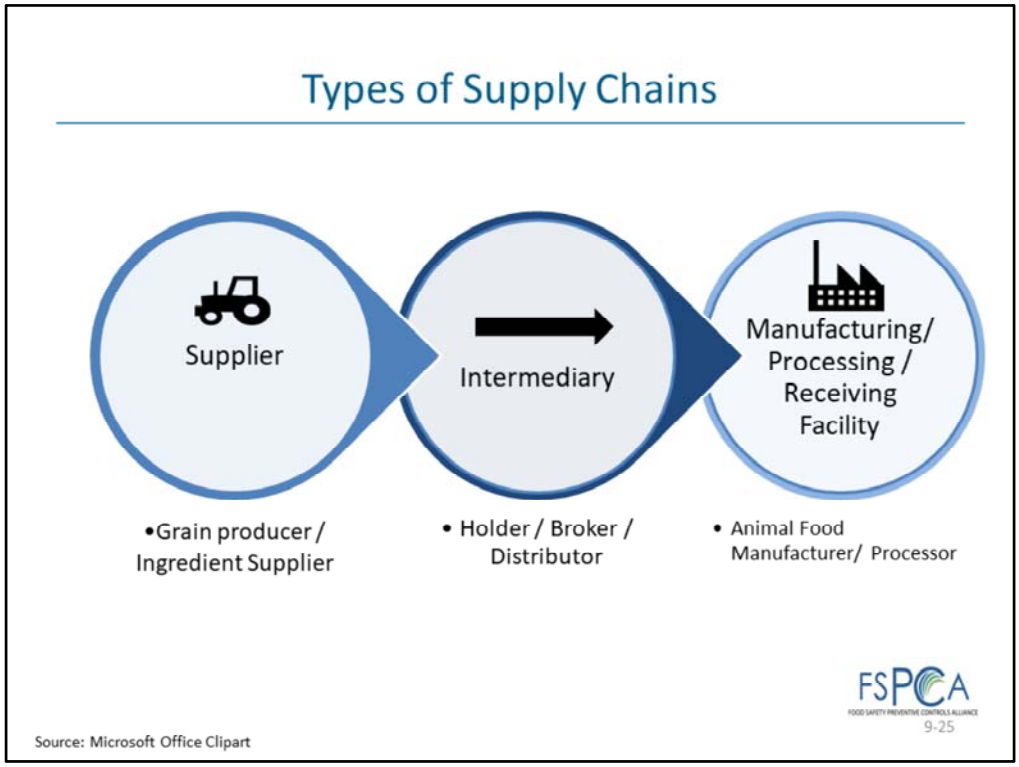
A receiving facility can rely on another entity, such as a broker or distributer, to conduct specified supply-chain program activities provided that the receiving facility reviews and assesses the entity's applicable documentation. The receiving facility must also document its review and assessment. The specific activities that other

entities can conduct are:

- Establishing written procedures for receiving ingredients from the entity
- Document that written procedures for receiving ingredients are being followed
- Determining, conduct, or both determine and conduct appropriate supplier verification activities

The only supplier verification activity that can be conducted by the supplier is sampling and testing. Suppliers can conduct and document sampling and testing for a particular lot of product and provide that information to the receiving facility. This testing is a type of supplier verification. The receiving facility must then review and assess the supplier's documentation and document this process.

The receiving facility may also rely on an audit provided by their supplier, as long as the audit is conducted by a third-party "qualified auditor".



The receiving facility must review and assess supplier verification activities that are determined by and/or conducted by another entity, and document the review and assessment activity. However, the receiving facility cannot rely on a supplier's determination of appropriate verification activities for its own product – the receiving facility needs to determine appropriate verification activities that are consistent with the animal food being produced. Thus, test results from a supplier are only acceptable if the receiving facility has determined that this is an appropriate verification activity for that animal food. Similarly, a supplier's self-audit or a supplier's review of their own records are not appropriate supplier verification activities. However, a supplier can provide an audit conducted by a third-party qualified auditor if the receiving facility has determined this is an appropriate verification activity for that animal food.

As noted above, another entity, such as a broker, may perform supplier verification activities for review and assessment by the receiving facility. Remember, the *supplier* is the entity that last manufactures or processes the product, grows the food or raises the animal; thus a broker is not a supplier in terms of the regulation. An entity other than the receiving facility may establish written procedures for receiving raw materials and ingredients from suppliers; document that the receiving procedures are followed; and determine, conduct and document appropriate supplier verification activities for those ingredients. The receiving facility may then

review and assess the other entity's documentation to verify that the supply-chain-applied control was appropriate for their food safety system.

(In cases where delivery of an ingredient is significantly delayed (such as in cases of severe weather), materials may be received from unapproved suppliers when those materials are subjected to appropriate verification activities.)
The facility must approve suppliers of ingredients requiring a supply-chain-applied control before receiving the ingredient. There must be written procedures for receiving ingredients; recall that such procedures were defined earlier in the chapter (21 CFR 507.3). The approval must be documented prior to receiving raw materials. These procedures must be established, followed, and documented to ensure that ingredients are received only from approved suppliers.

However, it is realistic to assume that there will be times when an ingredient is needed, but no approved supplier is able to provide it. Understanding this possibility, the rule allows, on a temporary basis, for the facility to receive an ingredient from an unapproved supplier. In these cases, the received ingredient must be subjected to appropriate verification activities before use.

(The types of verification activities listed here are examples from the *Preventive Controls for Animal Food* rule. Other verification activities may exist depending upon the facility and type of animal food.)

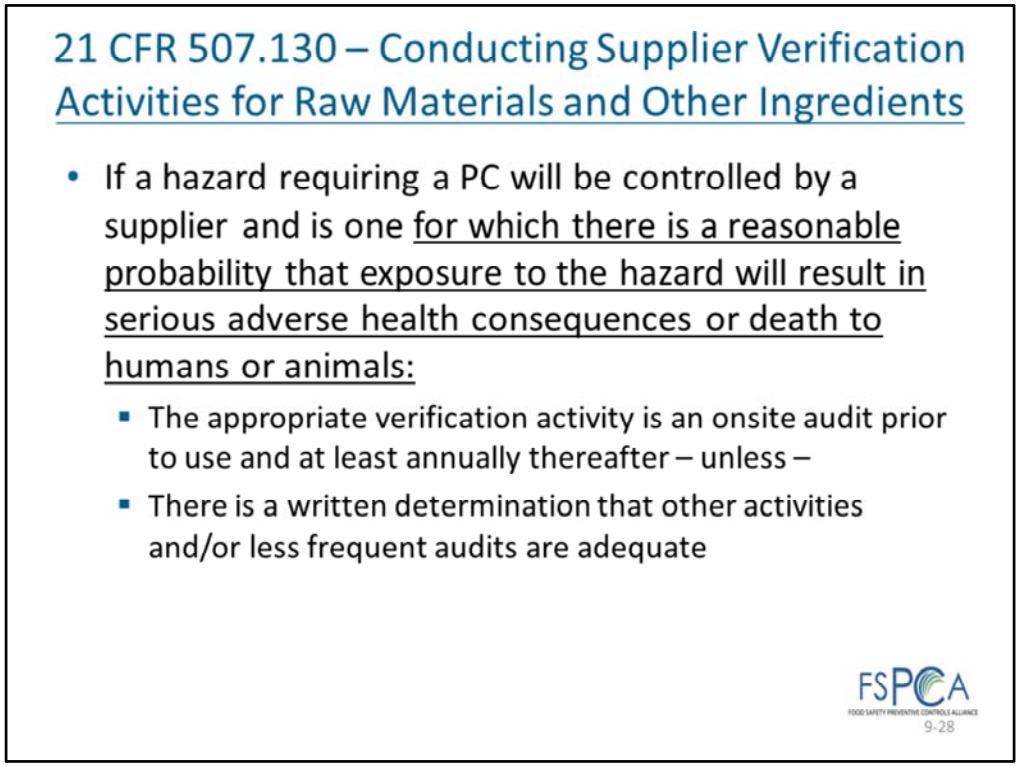
Once approved suppliers are identified, the receiving facility must identify and implement appropriate verification activities to ensure that the supplier actually controls the hazard requiring a supply-chain-applied control. The definition of verification for the supply-chain program is the same as for other preventive controls.

Verification is usually not conducted at the same frequency as monitoring activities. Typically, verification is conducted after preventive controls have been applied as a check that the system is operating according to the food safety plan. While some verification activities are performed for each lot (e.g., records review for in-house preventive controls), some supplier verification activities could be performed at a reduced frequency, depending on many factors, including the nature of the hazard and supplier performance.

Appropriate supplier verification activities are listed on the slide above. One or more of the following verification activities must be conducted before initial use and periodically thereafter for ingredients that require a supply-chain-applied

control.

- An annual onsite audit of food safety practices conducted by a qualified auditor.
- Sampling and testing of the supplier's product for the hazard of concern. This may be done by the supplier or the receiving facility.
- A review of the supplier's relevant food safety records, such as processing times and temperatures.
- Other procedures based on the risk associated with the ingredient and the supplier.

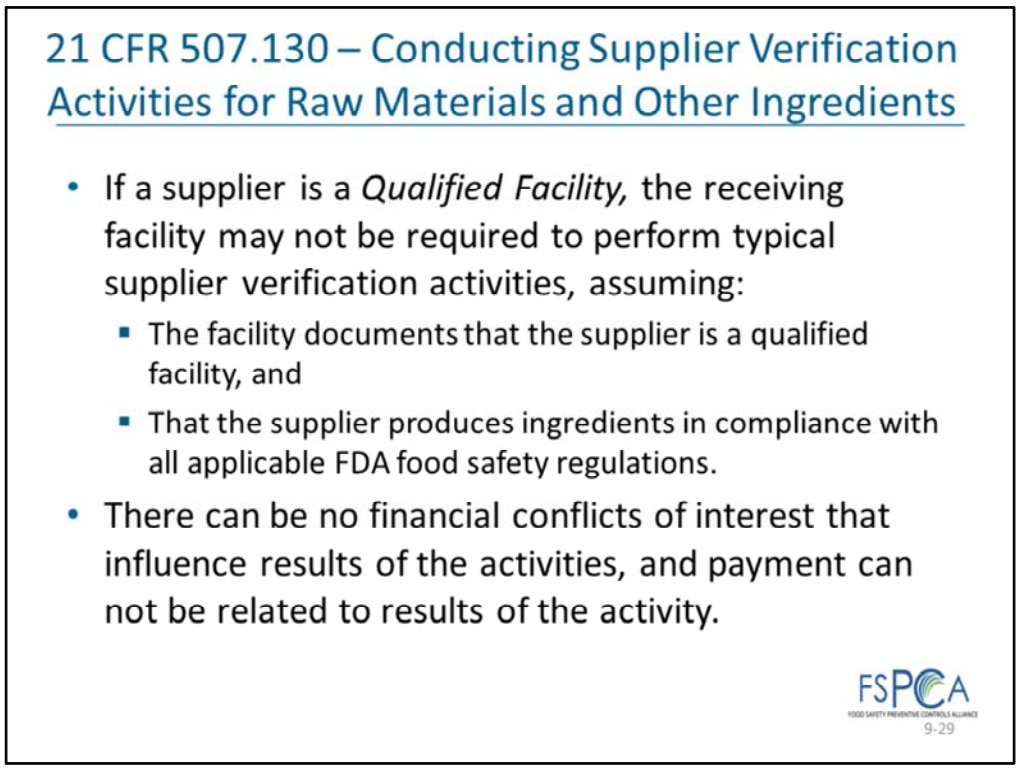


(There is no official list of “serious hazards” that “will result in serious adverse health consequences or death,” but the Reportable Food Registry requires reporting for these hazards. Many of these hazards were introduced in Chapter 3.)

In regards to supplier verification activities, there is a specific class of hazards requiring a preventive control that are identified in the rule as requiring an annual onsite audit. These are hazards for which "there is a reasonably probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals." FDA frequently refers to these by the name "SAHCODHA hazards." SAHCODHA hazards are not defined in the regulation but the terminology is in other places, such as for class I recalls and Reportable Food Registry reports. For SAHCODHA hazards only, FDA has specified that the appropriate supplier verification activity is an onsite audit. The audit has to be done before receipt of product and at least annually thereafter.

There is an exception, which allows the receiving facility to justify that there are other appropriate supplier verification activities for a SAHCODHA hazard and that an annual audit may not be required. This determination would need to be written and justification provided that the other activities or less frequent audits provide adequate assurance that the SAHCODHA hazard is being controlled. For example, the facility may be able to demonstrate that an audit every two years combined

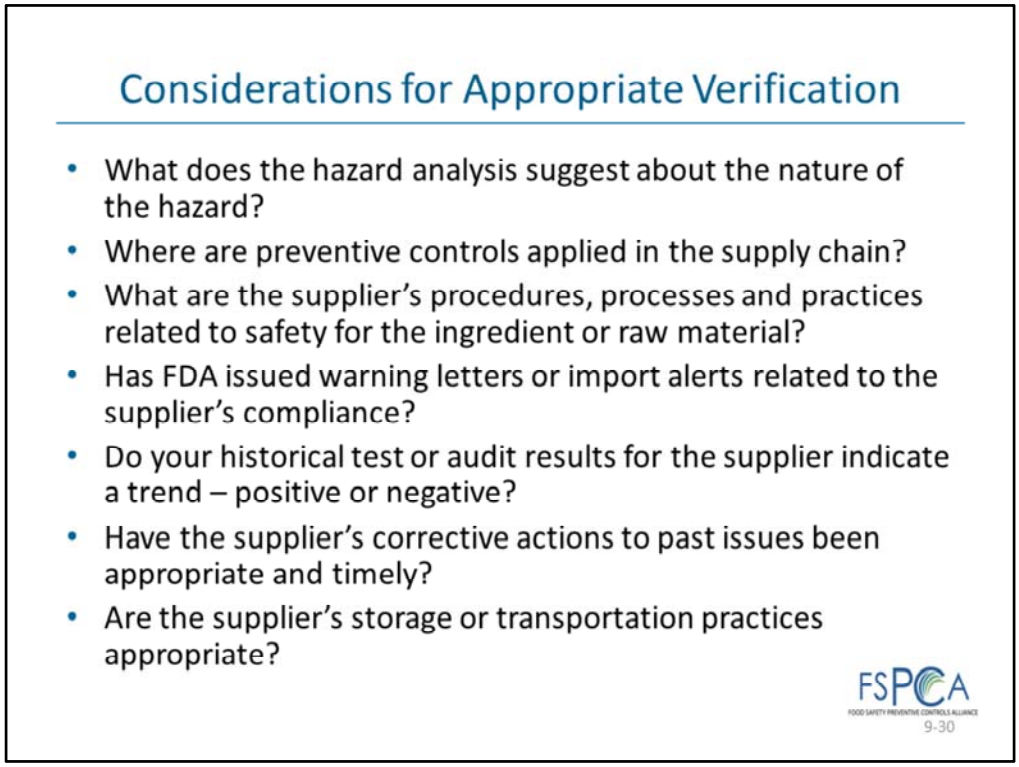
with periodic testing provides adequate assurance that the supplier is controlling the hazard.



If a supplier is a qualified facility (as defined by 21 CFR 507.3), a small produce farm, or shell egg producer with less than 3,000 laying hens, supplier verification activities are limited. The receiving facility does not have to conduct the same type of supplier verification activities previously discussed (onsite audit, sample and test, and record review). Instead, the receiving facility must obtain two different types of written assurance. When a qualified facility is the approved supplier, the first written assurance obtained by the receiving facility is an assurance that the supplier is a qualified facility as defined by 21 CFR 507.3. This assurance must be received before approving the supplier for an applicable calendar year and annually thereafter.

At least every two years the receiving facility must obtain a second written assurance from the qualified facility stating that the qualified facility complies with applicable FDA food safety regulations. The written assurance must include either (1) brief description of the controls for a hazard or (2) state that the facility is in compliance with applicable non-Federal food safety laws. For these suppliers, a receiving facility may use the absence of warning letters or other FDA compliance actions in determining whether to approve the supplier. Similar types of assurances must be provided for small produce farms and shell egg producers with less than 3,000 laying hens.

Lastly, this section of the regulation contains a conflict of interest provision related to supplier verification activities. This provision states that there can be no financial conflicts of interest that influence results of the verification activities and that payment can't be related to results.

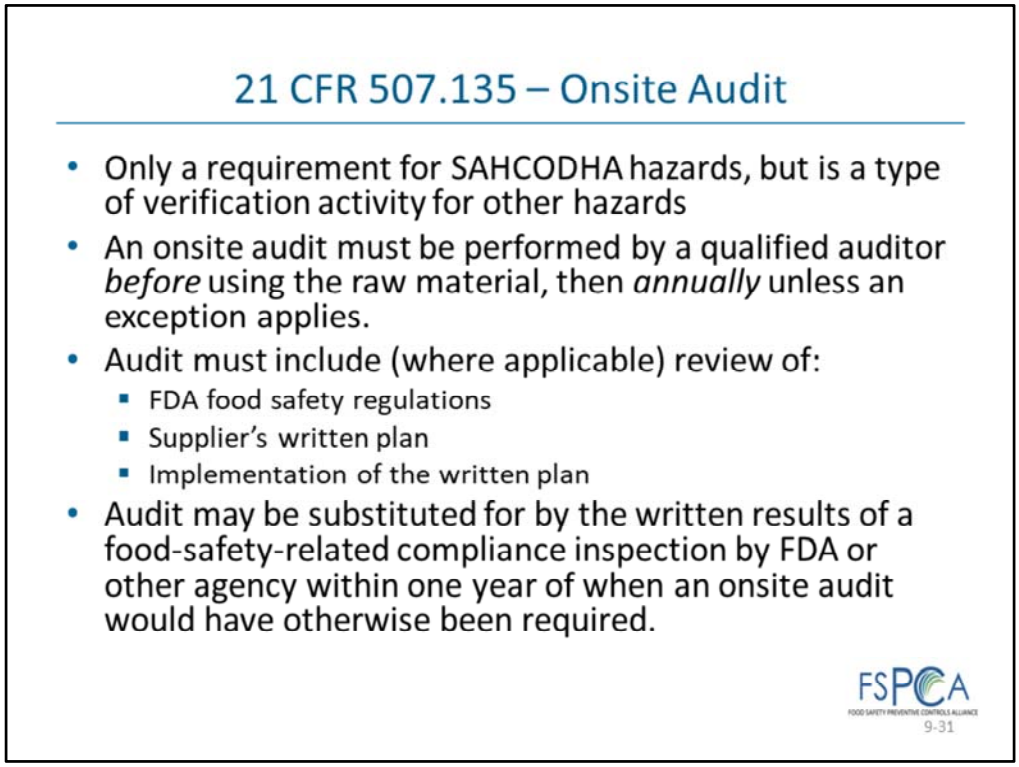


The verification activities used depend on the specific situation. The *Preventive Controls for Animal Food* rule requires consideration of the above in determining relevant verification activities. For example, when considering the hazard, is it likely to be present at high concentrations that would easily be detected by testing, or is the concentration expected to be so low that testing is unlikely to be reliable in detecting the hazard?

Where a preventive control is applied may also impact verification procedures. Knowledge of the supplier's procedures, processes and practices related to animal food safety may also influence verification procedures. Another consideration is a supplier's compliance history with FDA regulations. Warning letters and import alerts for a supplier may warrant taking extra precautions to verify that adequate controls are in place. Country of origin may be a consideration as well.

An ongoing relationship with a supplier is another important consideration. Some companies have many years of positive experience with a specific supplier, which may reduce the extent of verification activity needed. Conversely, constantly switching suppliers for an ingredient requiring a supply-chain-applied control may warrant heightened verification activity to build confidence in the supplier's ability to meet the facility's food safety requirements.
There may be other factors to consider, such as transportation and storage methods

used by the supplier, e.g., when an animal food requires refrigeration for safety.

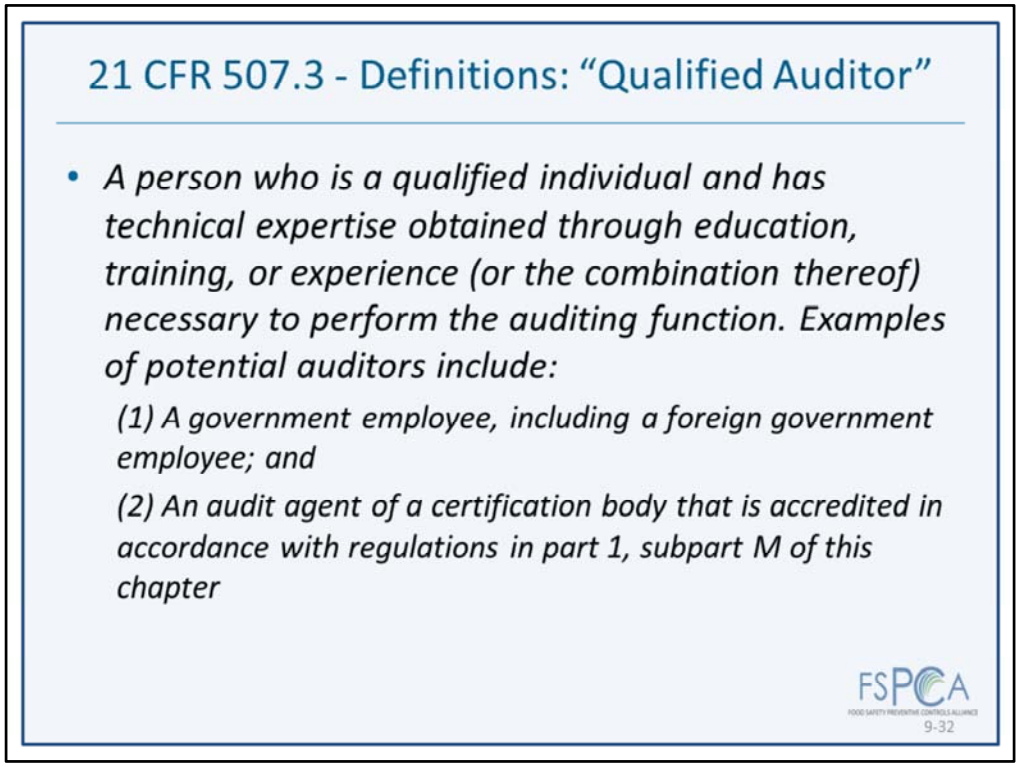


(Some companies use their own qualified employees to audit suppliers. Such audits allow first hand review of the critical food safety programs and preventive controls in place at the site. One can obtain a sense for how effective programs are by diligently reviewing program records, observing activities and interviewing line workers. While this type of audit allows a company to verify that their specific requirements are being met, it requires internal resources and expertise that may not be feasible for some companies. Audits conducted by an independent third party may also be used. Your supplier may be able to provide a third party audit for your review.)

There is not a requirement for an annual onsite audit except for SAHCODHA hazards. However, any audit conducted under the supplier verification program must be conducted by a qualified auditor. A qualified auditor (defined on the next slide) is one who has technical expertise to understand the hazard identified, the effectiveness of controls, and the requirements of the *Preventive Controls for Animal Foods* rule. Audits include both records review and observation of practices. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year than an audit focused only on the state of the facility at the time of the audit.
The audit must address process, sanitation, and supply-chain-applied controls, as well as CGMPs, as applicable. In addition, the audit must address, where applicable,

relevant FDA food safety regulations, the supplier's written plan, and the implementation of the written plan. Lastly, the audit must address the specific hazards identified in the receiving facility's hazard analysis.

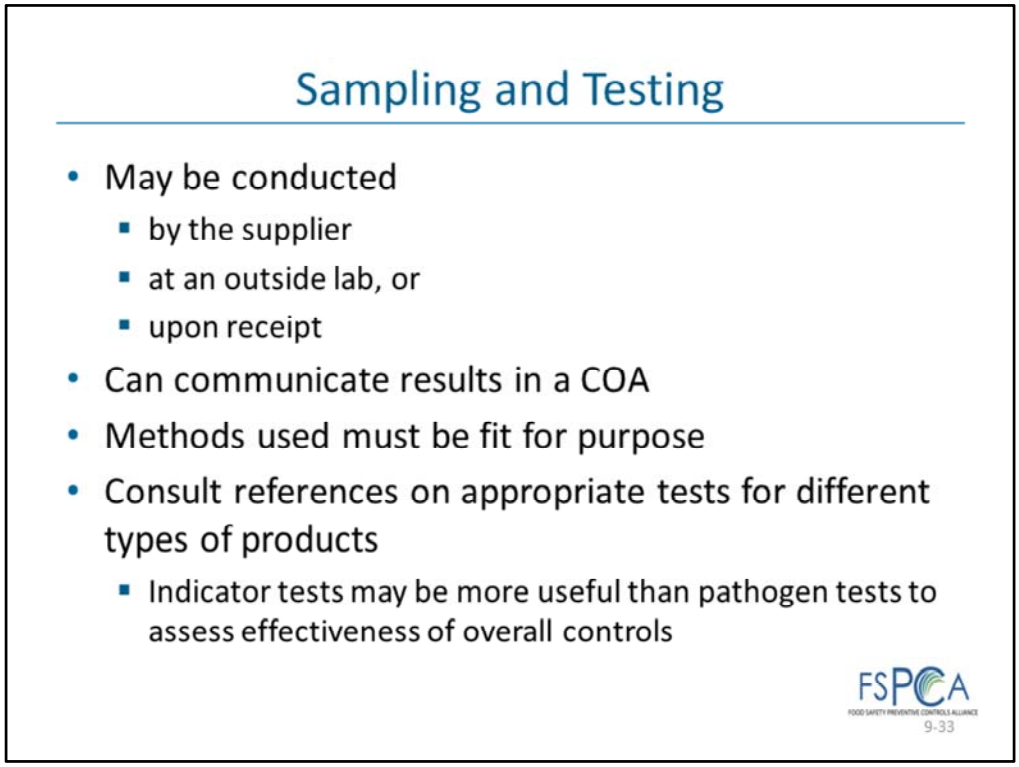
Some suppliers are routinely inspected by FDA or other recognized agencies. Thus, the receiving facility may be able to rely on the results of these inspections instead of a private party audit and obtain information on these inspections annually from the supplier. If used, such an inspection must be ''appropriate'' and be conducted for compliance ''with applicable FDA food safety regulations." In other words, the inspection must be sufficiently relevant to an onsite audit to be considered a credible substitute. Keep in mind that these inspections may not occur annually, and there is a requirement that an audit used in this way will have been conducted within one year of when an on-site audit would have been required.



(The "part 1, subpart M" referred to in this definition is the Accredited Third-Party Certification rule.)

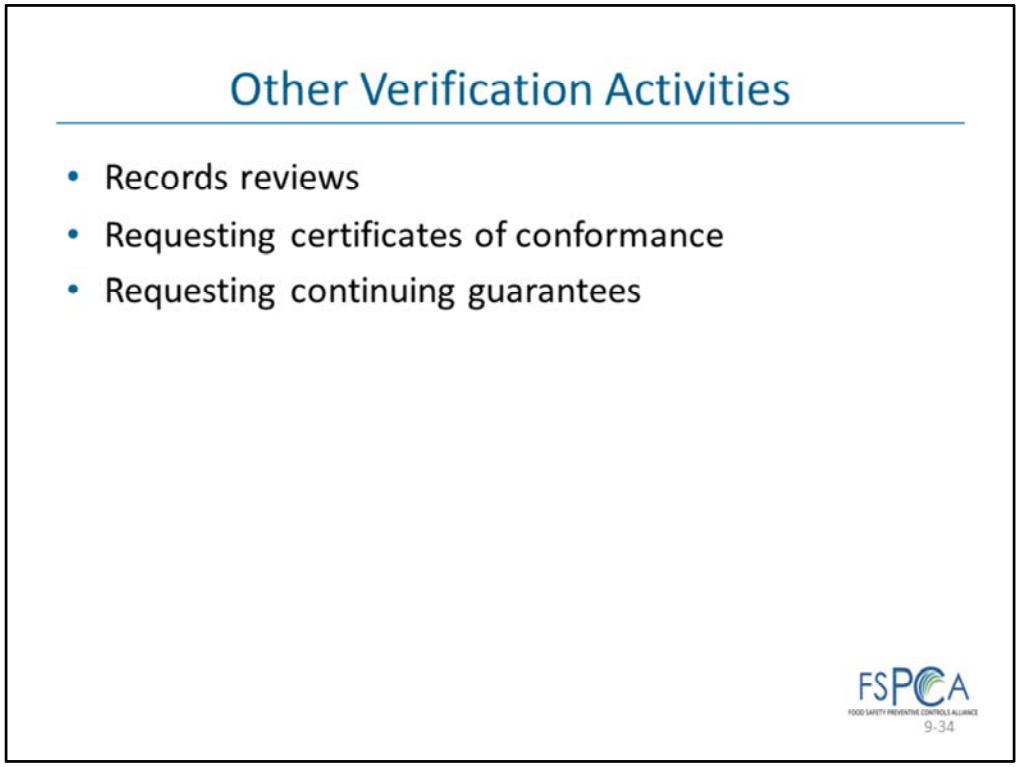
The definition of a qualified auditor is: *A person who is a qualified individual and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential auditors include:*

(1) A government employee, including a foreign government employee; and
(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter"

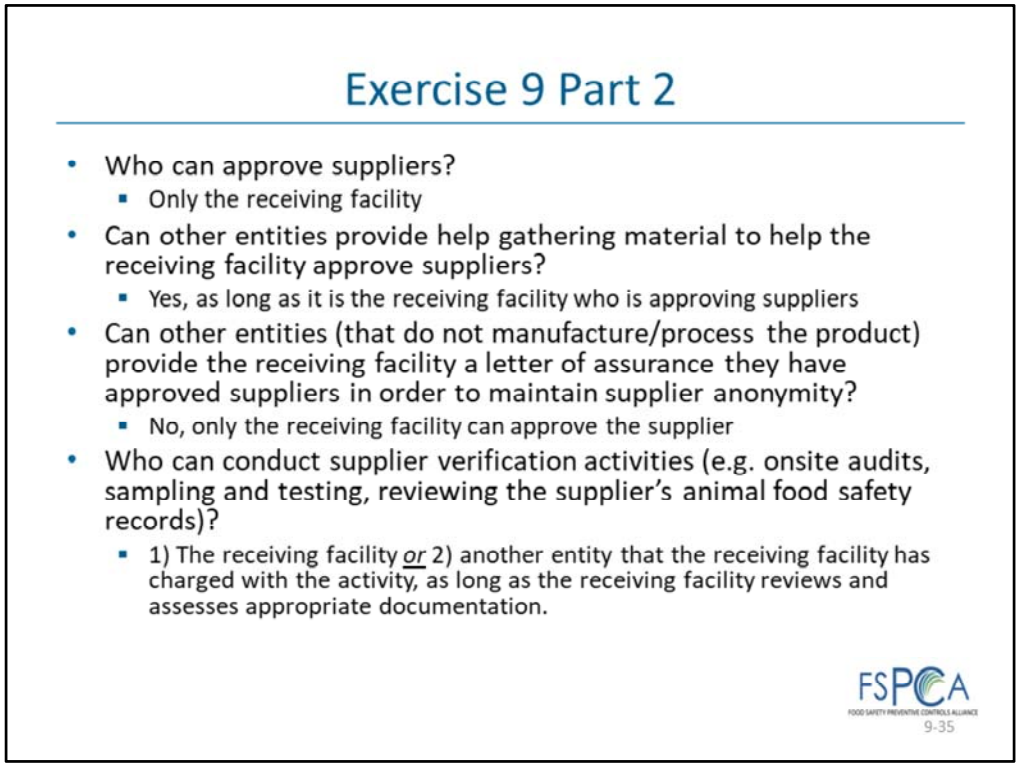


Testing of in-process materials, environmental samples, or the ingredient produced by the supplier may be appropriate as a verification activity if such testing provides meaningful results related to control of a hazard requiring a preventive control. Testing can occur at the supplier's facility, at an outside laboratory, or at the receiving facility. This test information would be captured in a Certification of Analysis (COA). When using sampling and testing, it is important to use methods that are fit for purpose and that the limitations of testing due to sampling probability are understood. The approach should depend on the potential hazards and the controls in place for the specific product. Testing for new supplier approval is usually more extensive than for maintenance of approved supplier status.

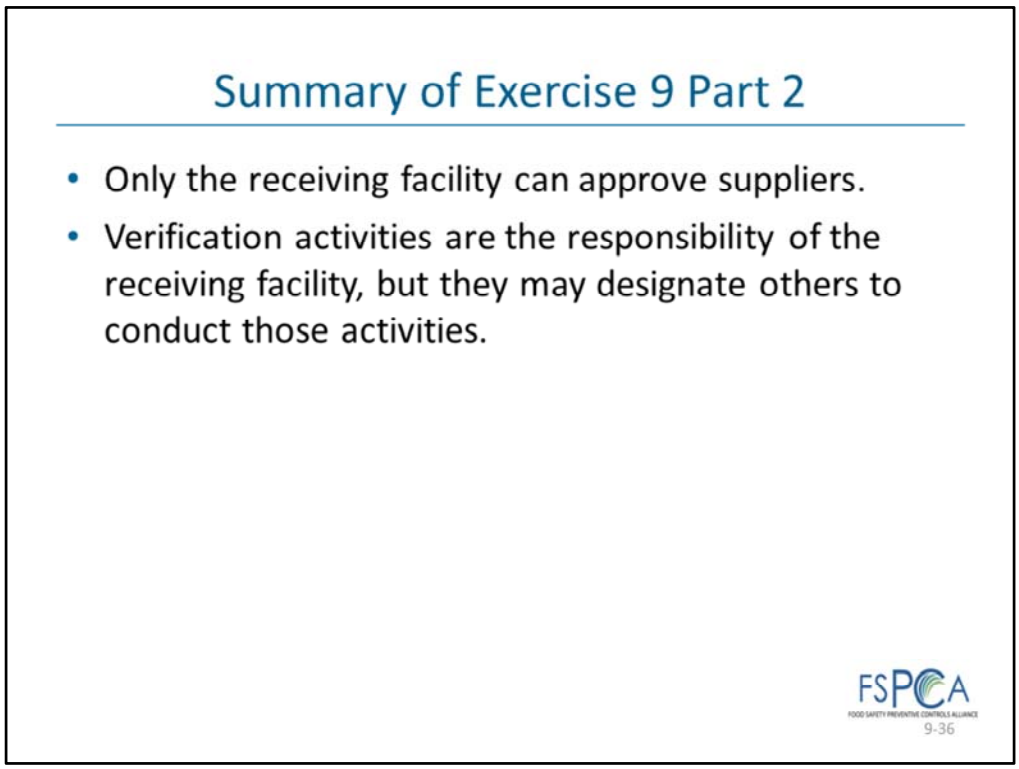
It is advisable to consult a reference book, a technical expert or other credible source to determine appropriate testing and sampling plans. Appropriate references may vary depending on types of food products and any related hazards identified. In some situations, references may identify indicator tests which might prove to be more useful to verify process control than specific pathogen testing. This may be the case when an indicator test provides more rapid results and is less expensive to conduct.



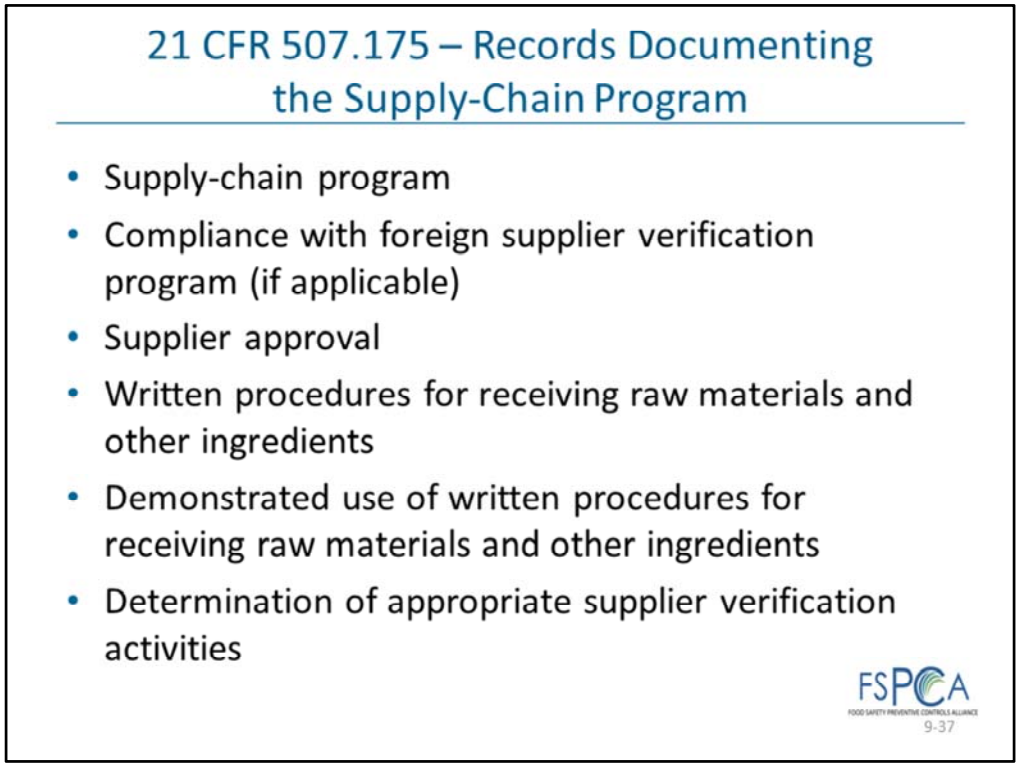
The PCQI may determine that other activities may be useful for supplier approval and verification depending on the hazards being managed. Companies may require their vendors to provide a Continuing Product Guarantee certifying that the product meets company requirements, including legal, regulatory, and conformance to specifications. These certificates generally cover multiple shipments or timeframes and should be reviewed and renewed at least annually or when requirements change. These generally do not serve as verification activities in the way that audits or testing (e.g., COAs) do, but may be suitable for certain ingredients, such as those with frequent government inspection. Further, they would not be the sole verification activity for compliance with the regulatory requirements. Copies of production records could also be reviewed to verify that the hazards were controlled and that material was produced to specifications.



Exercise 9, Part 2



Only the receiving facility can approve suppliers. Verification activities are the responsibility of the receiving facility, but they may designate others to conduct those activities.

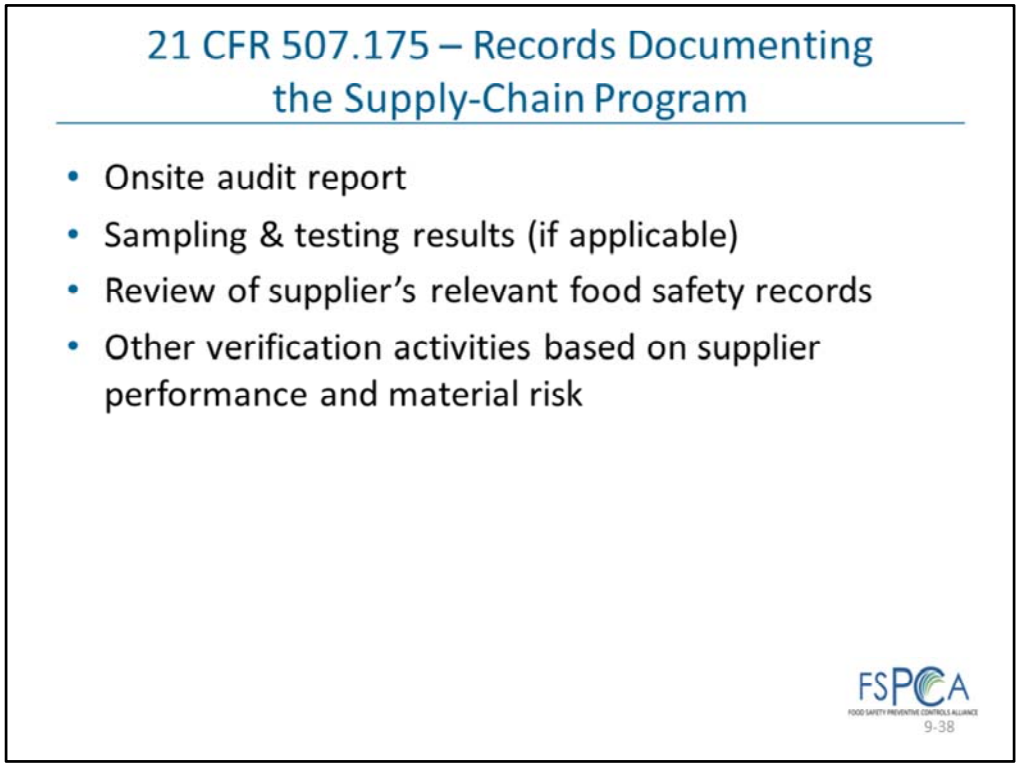


Animal food facilities, regulators, auditors, and customers view records as the historical method for confirming a program is in place and functional. Without records, one cannot demonstrate supplier programs are implemented as designed and are effective in controlling hazards.

Documentation is the starting point to describe how the facility develops and implements its supply-chain program. If the facility is an importer, then documentation that the facility is in compliance with the foreign supplier verification program (FSVP) requirements (21 CFR 1, subpart L) is required.

The facility must maintain documentation of approval for those suppliers that provide ingredients requiring a supply-chain-applied control. The receiving facility must also have written procedures for receiving raw materials and ingredients and maintain records that demonstrate that all raw materials and other ingredients with hazards requiring a supply-chain-applied control are received from approved suppliers, unless a specific exception applies as described previously.

The facility must document the determination of the appropriate supplier verification activities that will be conducted for raw materials and other ingredients requiring a supply-chain-applied control. Onsite audits, sampling and testing, review of supplier's relevant food safety records, or other approaches may be identified.

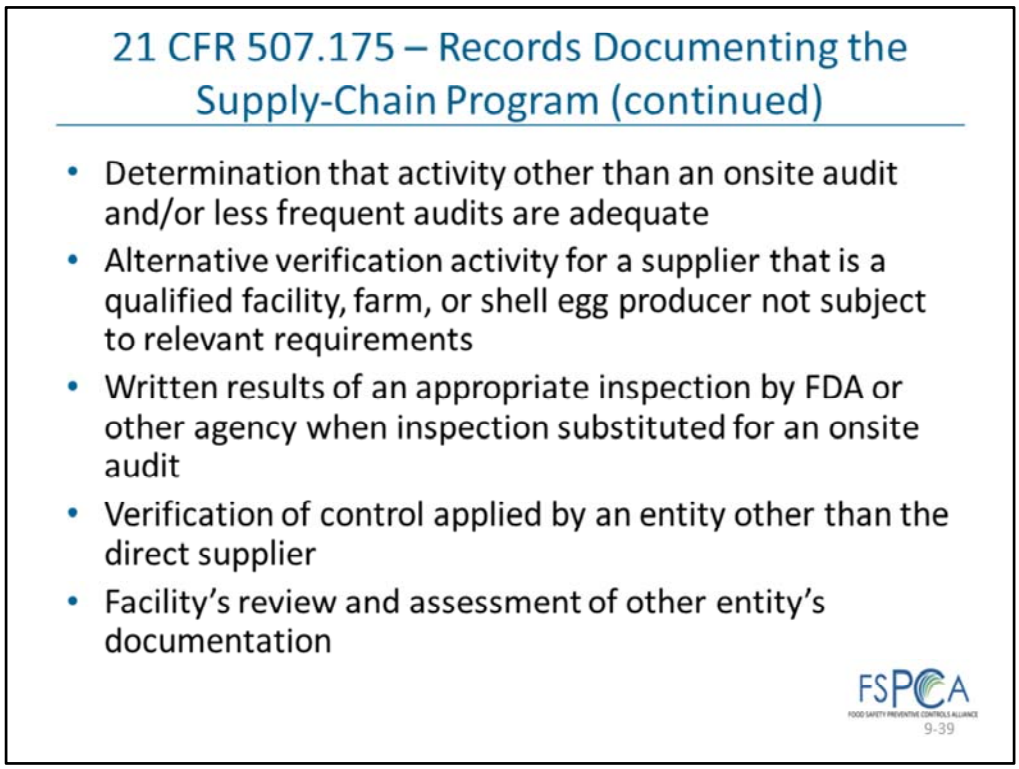


Records are necessary for all verification activities being conducted to ensure the supply-chain-applied is working.
Records of the onsite audits for approved suppliers are required. The records must include the supplier name, audit procedures, the date(s) the audit was conducted, the conclusions, and corrective actions taken in response to any significant deviations identified. Documentation that demonstrates that the audit was conducted by a qualified auditor is also required, which could be a receiving facility's employee if the employee meets the qualified auditor definition.

Records of sampling and testing must identify the ingredient tested, including the lot number as appropriate, and number of samples tested. The tests conducted and analytical procedure used, the date the tests were conducted, and the results must be documented. This information is usually documented on the laboratory test form, which would also specify the laboratory conducting the tests. Corrective actions, if any, must also be documented in response to the detection of hazards through sampling and testing.

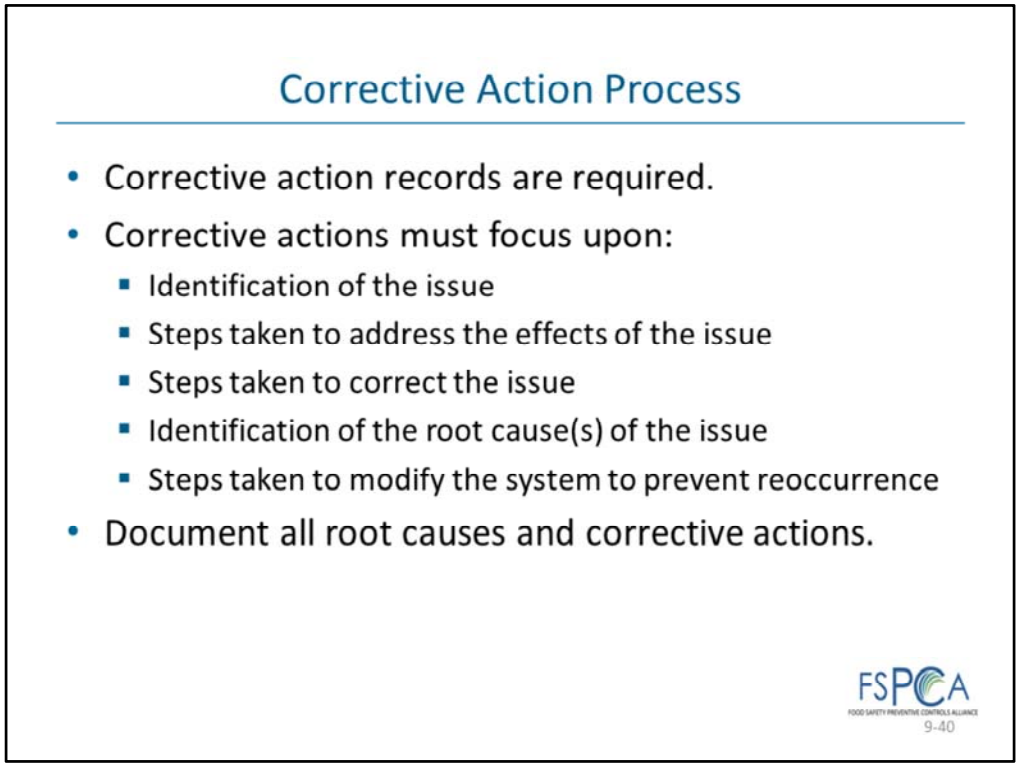
When the receiving facility or audit team reviews a supplier's food safety records, the receiving facility must document the name of the facility, date of the review, conclusions of the review, and corrective actions, if any, in response to deficiencies identified during review.

If verification activities other than those above are used, they must also be documented.



(The bullets on this slide are only as applicable. For example, if a company does receive ingredients from a *Qualified Facility*, there is no need for that documentation.)

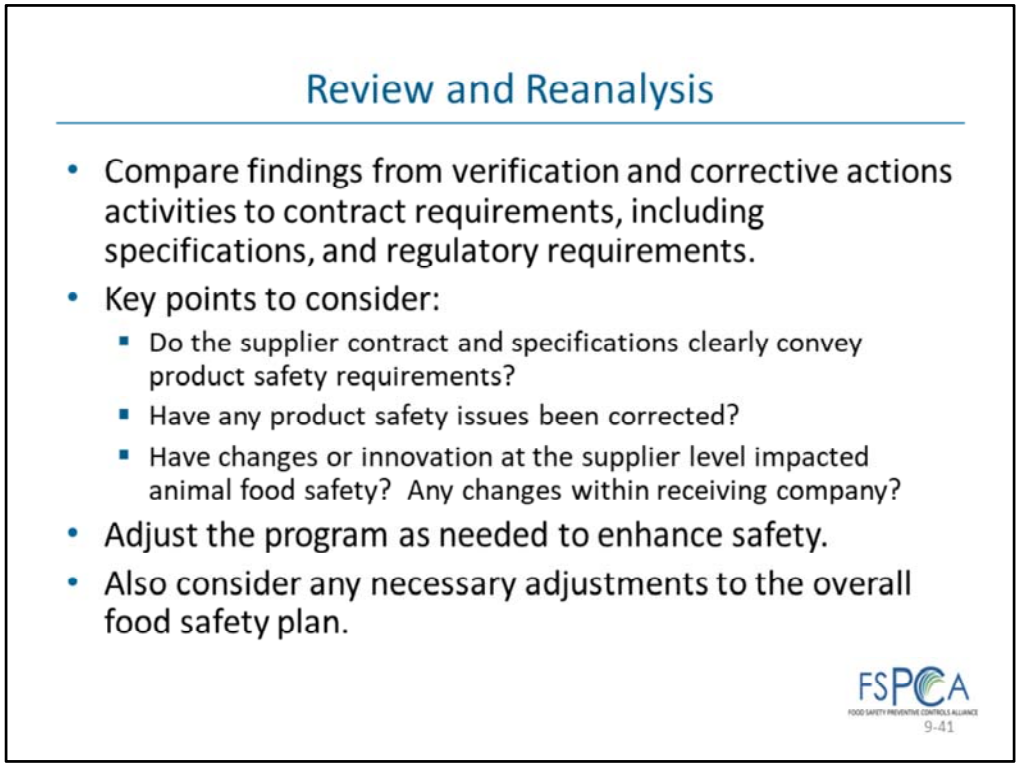
The slide above lists other documents that would be required, if applicable, to the facility. Each of these situations has been described previously in the chapter. It is possible that a facility could implement a supply-chain program without necessarily requiring these particular documents.



Corrective actions were introduced in Chapter 6 during the discussion of preventive control management components. For a supply-chain-applied control, corrective actions may be unique, given that they may very well occur outside of the facility.

When an audit or other verification activity identifies a gap in supplier performance related to a hazard requiring a preventive control, the receiving facility must ensure that the animal food being manufactured is not adulterated as a result of the supplier not adequately controlling the hazard. Corrective actions will vary depending on the issue as previously discussed in the other chapters on process and sanitation preventive controls.

Because system failures can occur in the supplier's process or procedures from time to time, the supplier must have a corrective action process for making modifications to prevent reoccurrence of an issue. The receiving facility must ensure that the intended corrective action is actually implemented. In addition, there must be an evaluation of all affected product for food safety to ensure that adulterated food does not enter into commerce. If adulterated product did enter commerce, then a recall would be required (see Chapter 10: Recall Plan).



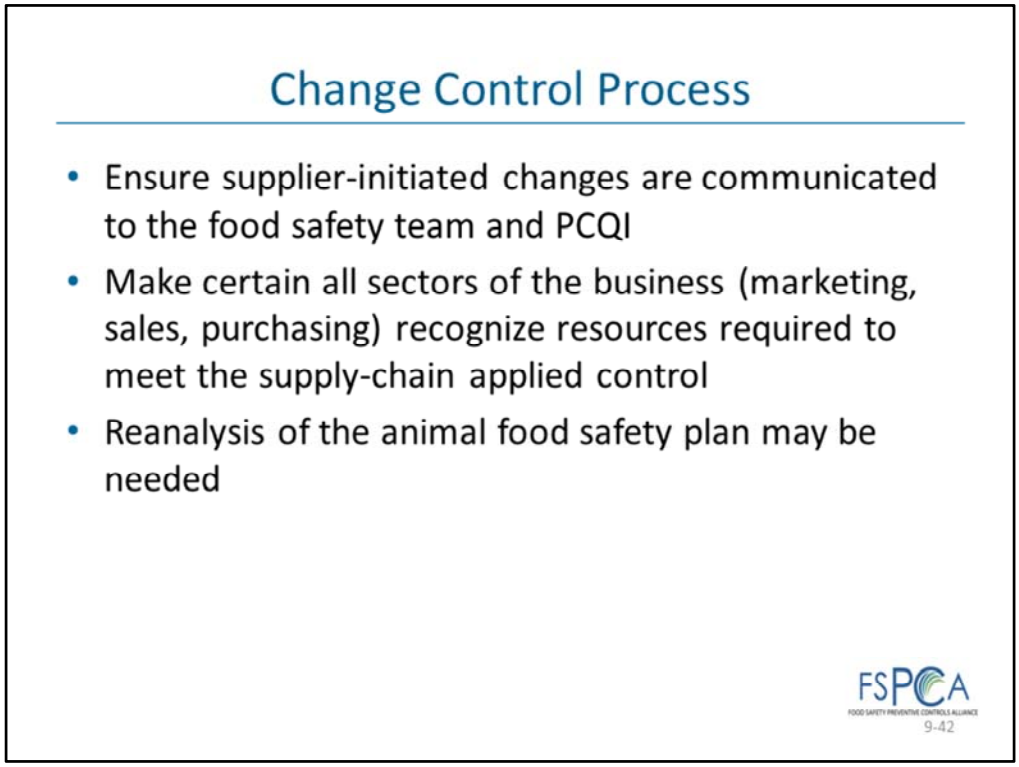
(These are good business practices, but not all are required by the *Preventive Controls for Animal Food* rule. The rule requires review and reanalysis of the food safety plan at least once every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.)

It is a good business practice to evaluate the supply-chain program on a routine basis (typically annually). Comparing findings from the supplier approval, verification, and corrective action processes against the safety requirements in the supplier specifications and contract may indicate the need for change. Raw material and other ingredient specifications should clearly communicate food safety requirements to the supplier, as well as identify these hazards for use in the supply-chain program.

If a food safety issue occurs with a product, there should be a review of the supply-chain program, including verification activities, to ensure that program inadequacy was not the cause. For example, the program may not have identified a hazard that is associated with an ingredient that needed to be controlled by the supplier. Also verify that the supplier took steps to prevent recurrence of issues, when applicable.

The receiving facility or the supplier may create new formulations or new processes.

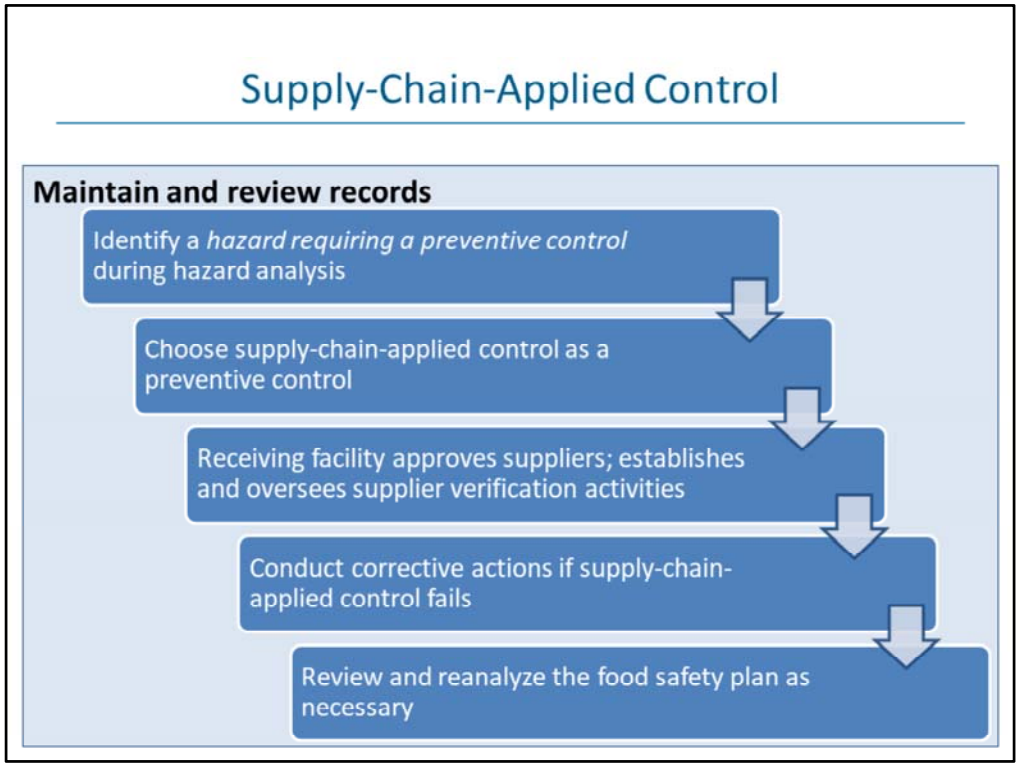
Any ingredient change should be reviewed to ensure that food safety requirements are still met by the supplier if the ingredient is associated with a hazard requiring a preventive control. Similarly, new hazards are periodically identified – ensure that the supply-chain program is adequate to address new hazards associated with the raw material or other ingredient that the supplier provides.



Change is a necessary part of the business process. Having procedures in place to accommodate changes can help avoid food safety or potentially disruptive supply-chain issues. Two aspects of change should be considered relative to suppliers – changes made by the supplier and changes made by the receiving facility. If suppliers make a change to the ingredients that they provide, the food safety team should be informed to allow reanalysis to determine if changes are needed to the food safety plan or supply-chain program. Frequently supplier communications are handled by purchasing; thus the purchasing team must forward relevant information to the food safety team. The supplier should understand the importance of reporting all changes to customers so they can analyze the change with respect to their use of the ingredient.

Conversely, the receiving facility and/or its purchasing team may identify a new supplier that can provide a similar ingredient. It is essential that purchasing not make a switch in suppliers of an ingredient or raw material associated with a hazard requiring a supply-chain-applied control without the authorization of the food safety team. The new supplier must be approved if the ingredient is associated with a hazard requiring a supply-chain-applied control. Again, it is important to consider the resources needed to review supplier programs for new suppliers from a food safety perspective before switching suppliers. Reanalysis of the Food Safety Plan may also be relevant for company-initiated supplier changes, especially those for

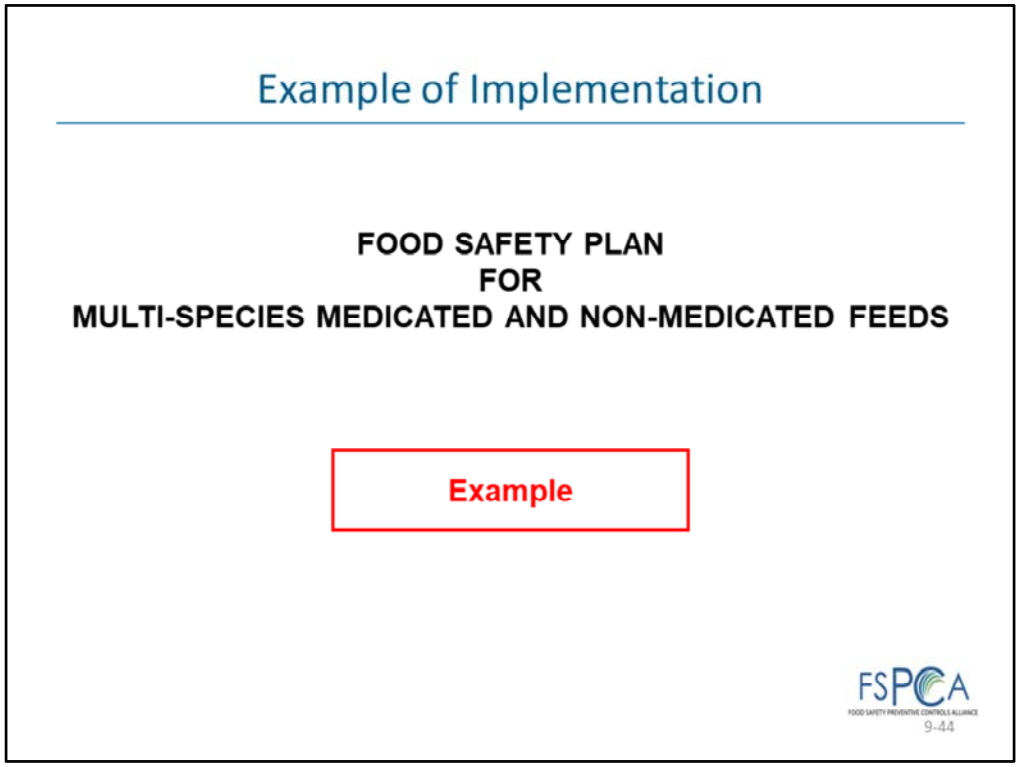
ingredients with hazards requiring a preventive control.



This slide summarizes the supply-chain-applied control. The major components of the program are:

- The hazard analysis identifies a hazard requiring a preventive control.
- A supply-chain-applied control is chosen as the appropriate control.
- The receiving facility establishes and conducts supplier verification activities.
- If any deficiencies are identified, corrective actions are implemented.
- The supply-chain program undergoes review and reanalysis. The need for review and reanalysis may arise as necessary, due to time since the last review, implemented corrective actions, or new information becoming available.
- Review and reanalysis may lead to further hazard analysis, thus restarting the cycle.

For all of these actions, records must be generated, maintained, and reviewed in accordance with requirements established in the *Preventive Controls for Animal Food* rule.



The following slides provide an example of how a supply-chain-applied control may be utilized in a food safety plan. To demonstrate these concepts, we will pick back up with the copper toxicity example first described in Ch. 5 and 6 in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds.

Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 1. Hazard Analysis

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	C	Copper toxicity

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9-45

(In the example plan, copper toxicity is the second listed identified chemical hazard for ingredients, thus the designation of C2.)

In the example plan, copper toxicity is a known or reasonably foreseeable chemical hazard if the sheep mineral premix is received with an incorrect copper concentration.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 1. Hazard Analysis

Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify *Known or Reasonably Foreseeable Hazards*	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Copper toxicity in sheep	I – High	B - Medium	Yes	Multispecies premixes used by facility, copper toxic to sheep

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9-46

In Chapter 5, the determination of severity and probability was discussed. Because excess copper can be extremely toxic to sheep and the facility uses multiple premixes, it was determined that the hazard required a preventive control. The extreme toxicity can lead to death in sheep, and so the facility considers this to be a SAHCODHA hazard.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 1. Hazard Analysis

Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Copper toxicity in sheep	Supply-Chain-Applied Control - Control of copper level in sheep mineral premix	1

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9-47

The facility receives multiple trace mineral premixes, all purchased from the same supplier. With this being the case, the facility determined that the appropriate preventive control is a supply-chain-applied control to ensure that the incoming sheep trace mineral premix does not contain excess copper. This could potentially happen if a mixing or sequencing error occurred at the supplier. This is Preventive Control #1 identified in the example food safety plan.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls

Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
Hazard Requiring a Preventive Control	Appropriate Control for *Hazard Requiring a Preventive Control*	Preventive Controls Number	Preventive Control Category	Parameters (if applicable)
Copper toxicity in sheep	Control of copper level in sheep mineral premix	1	Supply-Chain-Applied Control	n/a

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9-48

Table 2 identifies the preventive control category as being a supply-chain-applied control. There are no parameters (minimum or maximum values) associated with supply-chain-applied controls because the control is applied at the supplier and not at the facility, Thus, 'n/a' for 'not applicable' is placed in the table.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls

Preventive Control(s)	Management Components			
(1)	(6)			
Hazard Requiring a Preventive Control	Monitoring (if applicable)			
	What	How	Frequency	Who
Copper toxicity in sheep	n/a	n/a	n/a	n/a

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
9-49

(The monitoring row has n/a for not applicable because this example is for the receiving facility. Monitoring is not a required management component for receiving facilities if controlling a hazard through a supply-chain applied control. Instead, the monitoring is conducted by the supplier.)

Supply-chain-applied controls are no subject to the preventive control management component of monitoring. Thus, n/a is placed in the monitoring section of the table.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls

Preventive Control(s)	Management Components	
(1)	(7)	(8)
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records
Copper toxicity in sheep	Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate	COA from supplier; Records reviewing the COA by supplier; Supplier approval and verification documentation; Record of annual audit

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Every incoming lot of sheep trace mineral premix must be accompanied by a Certificate of Analysis (COA), demonstrating that the premix contains an accurate copper concentration for sheep. This COA is to be the result of test-and-hold procedures at the supplier. If the COA is not present, the shipment must be rejected. If a failure occurs, and a shipment is erroneously accepted, the disposition of the premix must be determined, and the recall plan initiated if necessary.

In addition to the applicable COAs and records of their review, records are also generated and retained in accordance with supplier approval and verification requirements. This includes the approved status of the supplier, as well as records of annual third party audits of the supplier due to copper toxicity being considered a SAHCODHA hazard.

Livestock Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 3. Description of Preventive Control Verification Activities

Activity	Description of Activity
Type of Validation	n/a
Supplier Verification Activities	○ Onsite audit ○ Uses COAs for assurance of incoming Cu concentration ○ Quarterly analysis of sheep trace mineral premix by the supplier to verify proper copper levels do not exceed the values established through the supply-chain-applied control via a certificate of analysis ○ Reviewing the records of the supplier's food safety plan for sequencing and flushing procedures to prevent carryover of copper into the sheep trace mineral premix
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

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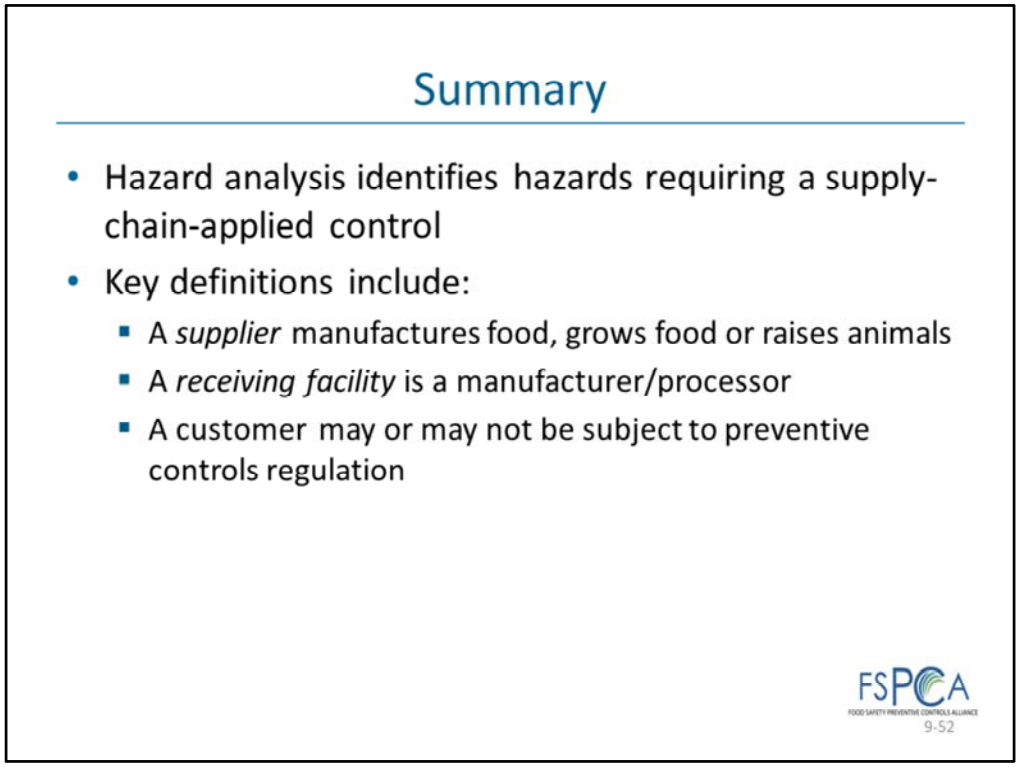
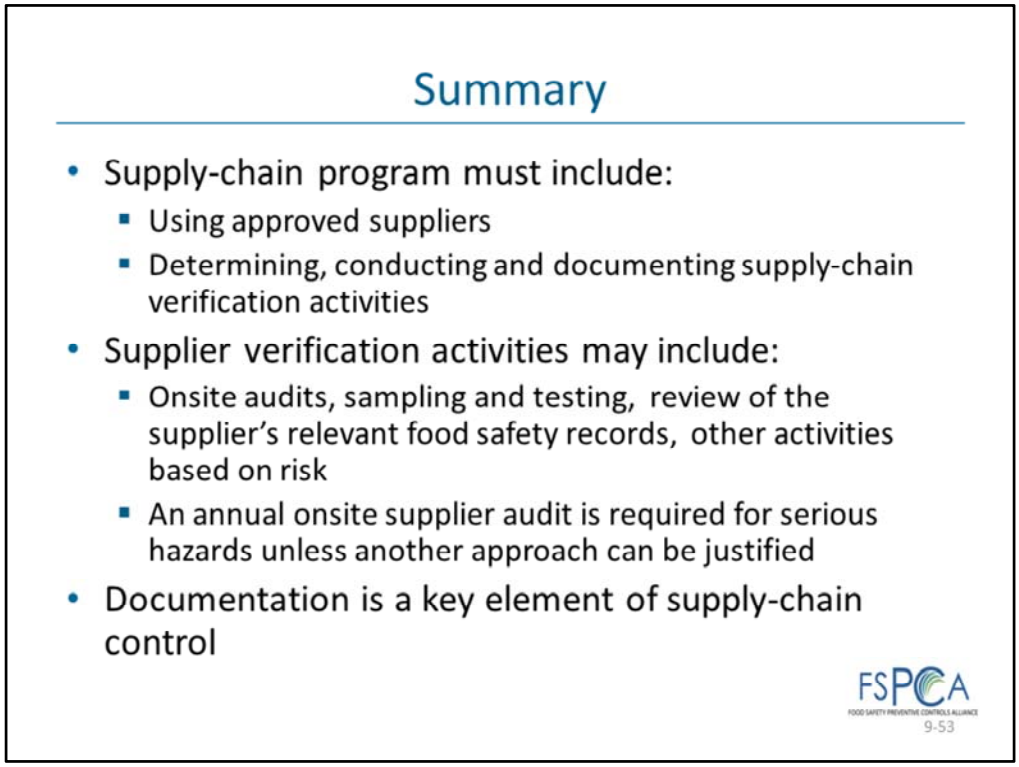
There is no validation required for supply-chain-applied controls.

The verification activities include an onsite audit by the receiving facility because copper toxicity was identified as a SAHCODHA hazard. The facility also receives COAs with each batch of ingredient from the approved supplier. In addition, there is quarterly analysis of the sheep trace mineral premix by the supplier to verify proper copper levels and they do not exceed the valued established by a certificate of analysis. There is also review of the records of the relevant parts of the supplier's food safety plan (descriptions of the sequencing and flushing procedures used to ensure that copper carryover is prevented).

A reanalysis of the plan is conducted every three years, as necessary when changes occur, or when it is determined that a preventive control is ineffective.



In summary, a supply-chain program is an essential element of a food safety system. The hazard analysis process identifies hazards requiring a supply-chain-applied control for which a supply-chain program must be implemented. The supplier is the entity that manufactures or processes an ingredient or grows the food that the receiving facility uses to make the product.



The supply-chain program must include using approved suppliers, and determining, conducting, and documenting supply-chain verification activities. Verification activities may include onsite audits (required for SAHCODHA hazards unless another approach is justified), sampling and testing, review of a supplier's relevant food safety records, and other activities based on risk. Records that document all of these activities must be maintained to demonstrate that the supplier program is operational and effective.

It is very important that any changes that may impact the supply-chain program are addressed as necessary. Managing a supply-chain program is a complex activity. Therefore, all parties involved, including both within and outside the receiving facility, should understand the importance of the program and the resources necessary to implement it effectively.