Chapter 9. Supply-Chain-Applied Controls

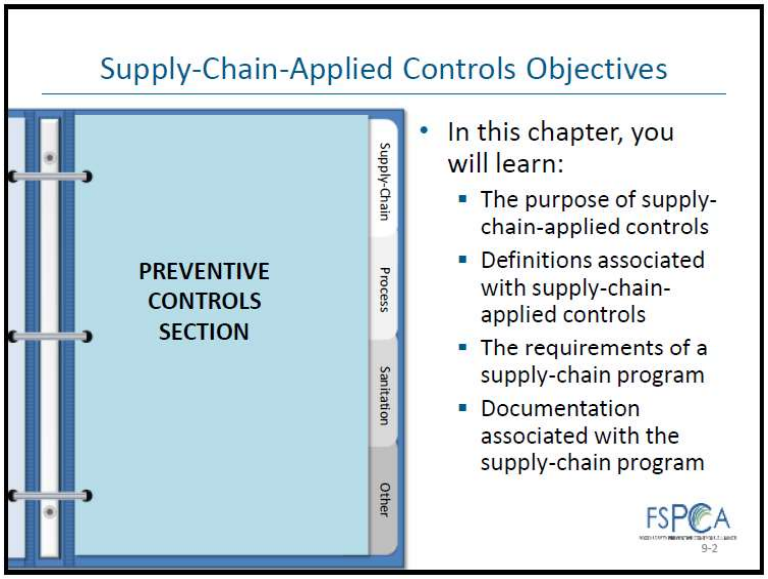
The Supply-Chain Program described in this chapter is not the same as a supply chain program typically thought of by the animal food industry. In fact, Supply-Chain-Applied Controls may have limited applicability to animal food. The predominant application of Supply-Chain-Applied Controls is expected 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.

Slide 1

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.

See the FSPCA website for information on the FSPCA Foreign Supplier Verification training program.

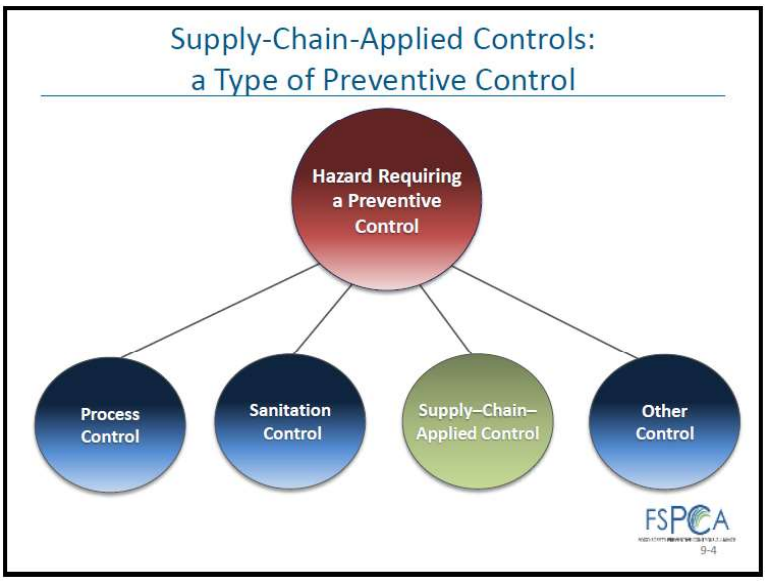
Slide 2

In this chapter, participants will learn the purpose of Supply-Chain-Applied Controls, and their role in an animal Food Safety Plan. The Supply-Chain Program relies heavily on key definitions of terms, such as supplier and receiving facility, so those will also be described. The requirements of the Supply-Chain-Applied Controls, as well as associated documentation, will also be covered.

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 the 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.

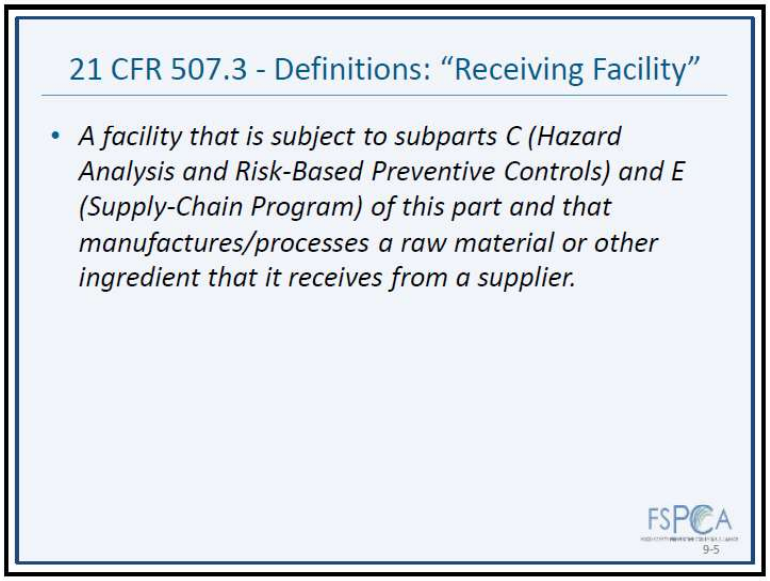
Slide 3

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.



Slide 4

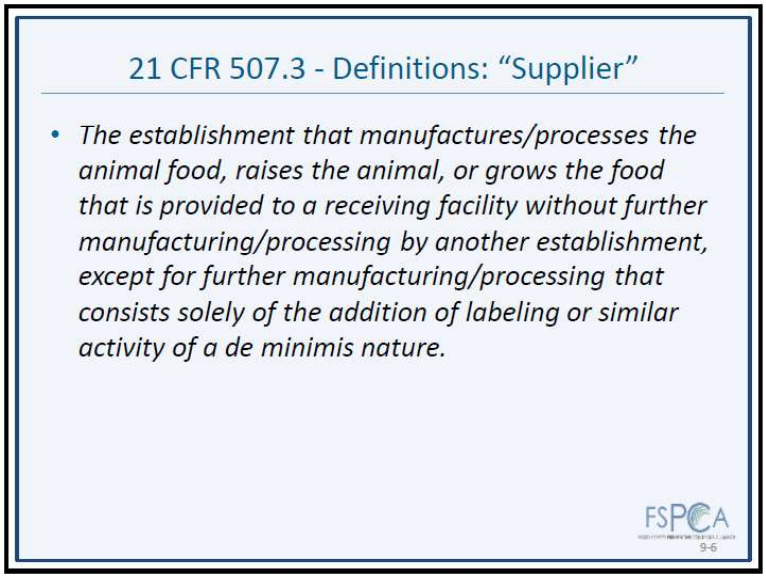
As discussed in Chapter 5, 21 CFR 507.34 introduces the concept of and basic requirements for preventive controls. Recall that a preventive control is required only when the facility has identified a hazard requiring a preventive control. Preventive controls are required to significantly minimize or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



Slide 5

There are multiple definitions that are relevant to the Supply-Chain Program. The first two definitions covered in this chapter, receiving facility and supplier, describe "who" does what in the supply-chain program.

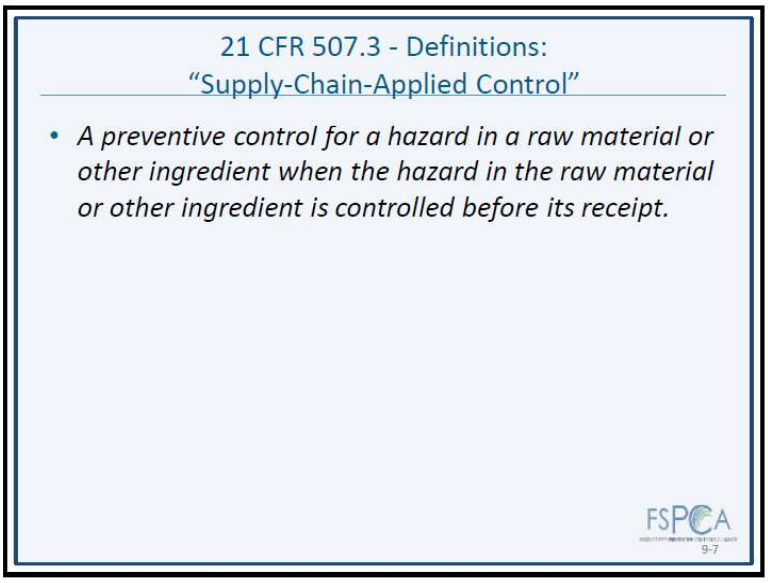
A receiving facility is "*A facility that is subject to subparts C (Hazard Analysis and Risk-Based Preventive Controls) and E (Supply-Chain Program) of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier."* While the *Preventive Controls for Animal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



Slide 6

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.



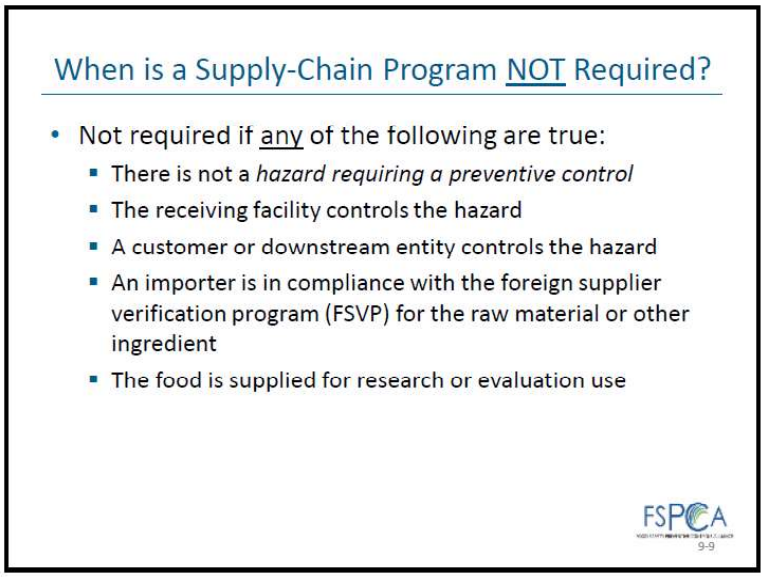
Slide 7

The third key definition is for a "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. These definitions, as with all others, are found in 21 CFR 507.3, which begins on page 56338 of the *Preventive Controls for Animal Food* rule.

Slide 8

During the hazard analysis process, the facility must first identify a hazard requiring a preventive control in a raw material or other ingredient. During the hazard analysis and preventive controls determination process, the facility determines if a Supply-Chain-Applied Control is necessary to control an identified hazard requiring a preventive control. This type of preventive control is only necessary if the agent is a *hazard requiring a preventive control* and the receiving facility needs a supplier to control the hazard. 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 (such as a process control) to control the hazard itself.

The hazard analysis may indicate that an ingredient and its supplier do have an association with a specific food safety hazard but the receiving facility 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 receiving 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.



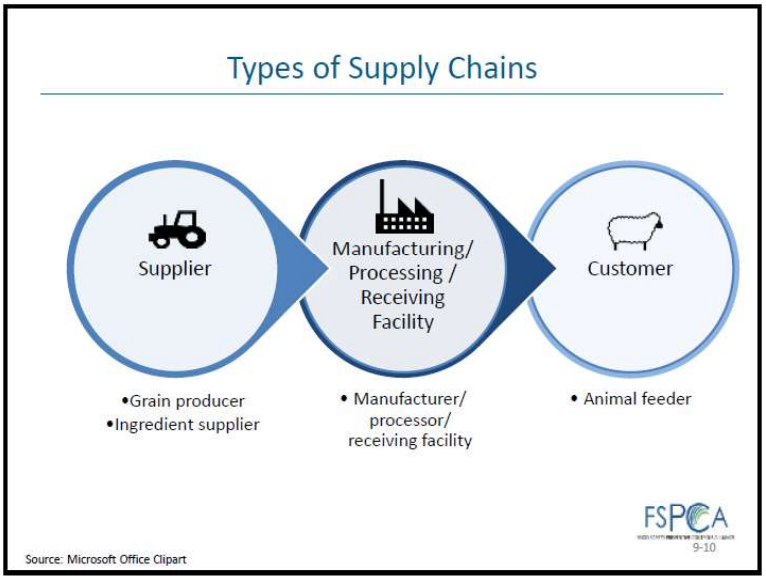
Slide 9

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

1. The hazard analysis concludes that the hazard is not a *hazard requiring a preventive control*
2. The receiving facility controls the hazards requiring a preventive control within the facility such as with a process or sanitation control
3. When a customer or downstream entity controls the hazard (see Slides 5-24 and 5-25 for a discussion on customer control of the hazard)
4. When an importer of the raw material or other ingredient is in compliance with the FSVP
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)

In order to not implement a Supply-Chain-Applied Control due to the food's use for research or evaluation, the following must occur:

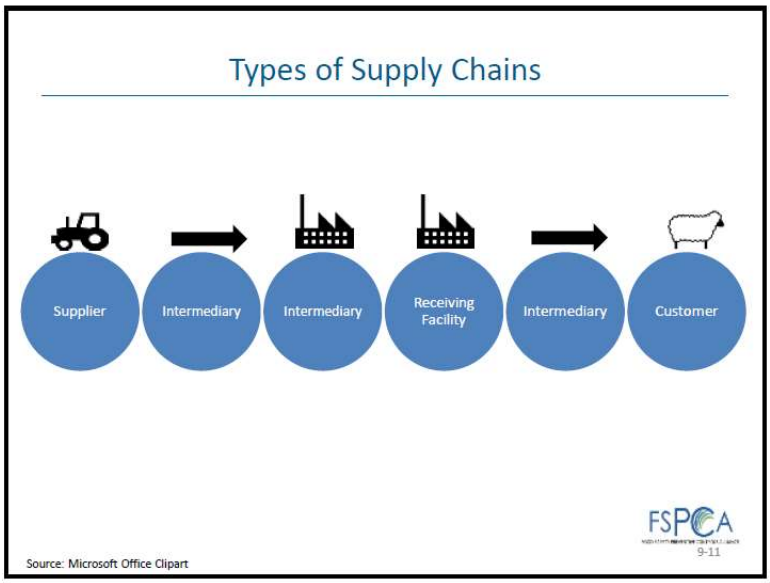
- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled "Food for research or evaluation use;"
- The food is supplied in a small quantity consistent with a research, analysis, or quality assurance purpose, it is used only for that purpose and unused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



Slide 10

To understand the requirements of the Supply-Chain Program, it is important to understand the definitions of supplier and receiving facility 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.

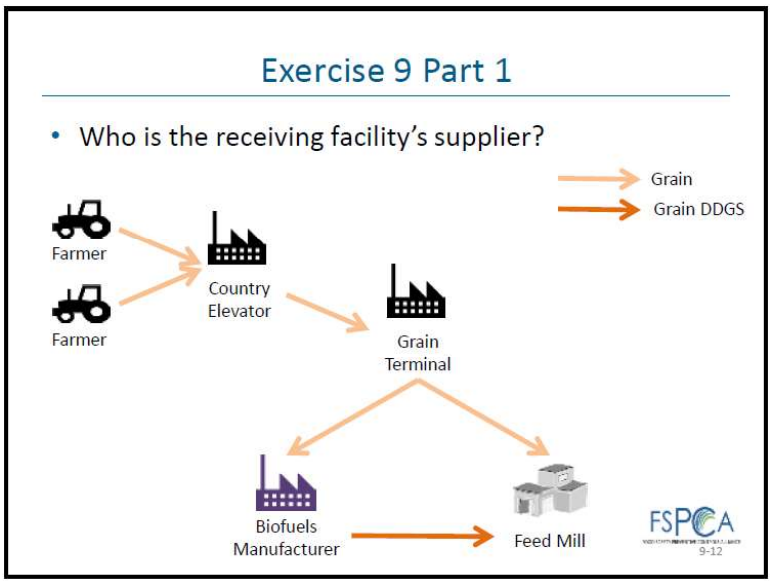


Slide 11

In reality, most supply chains are much more complex than the previous example as there are often intermediaries between an ingredient supplier, the receiving facility, and the ultimate customer (animal feeder). In this example, the supplier is a vitamin manufacturer. The supplier sells his product to a broker (the first intermediary) that does not take possession of the vitamin. The broker sells the product to another entity (second intermediary) that re-labels the vitamin. Because this entity does not conduct additional manufacturing/processing and simply re-labels the product, this person is not considered a "supplier" by definition in 21 CFR 507.3. The second intermediary sells the product to the receiving facility which uses the vitamin to manufacture animal food. The receiving facility than sells the product to a different broker (third intermediary), who does not take possession of the product. The broker then sells the product to the customer who feeds the animal food.

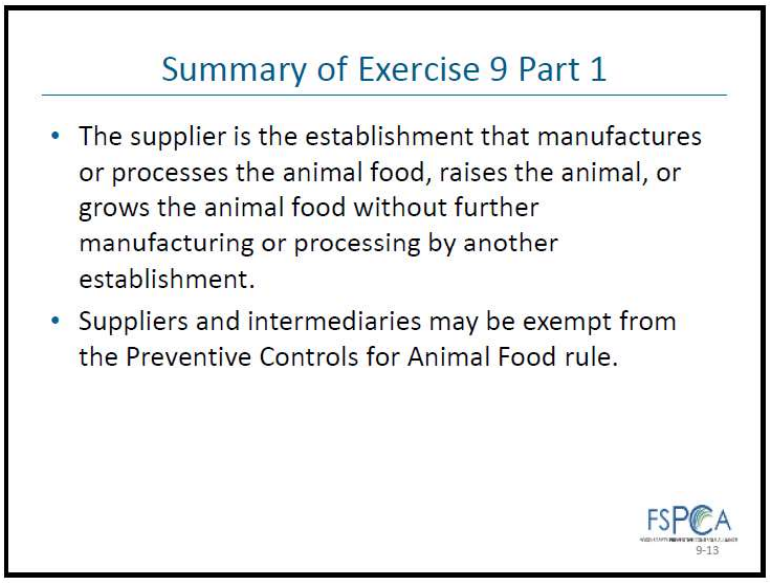
In the example above, the receiving facility is the animal food manufacturer. Although the receiving facility purchased the product from the second intermediary, under the definitions for the supply-chain program provisions the facility's "supplier" for the vitamin ingredient is the vitamin manufacturer because that is the last entity that manufactured the animal food without further processing.

When a facility is considering the implementation of a supply-chain-applied control, the facility must consider the practicality of such a control for their facility and must be able to identify (and approve) their supplier. Identifying the supplier may be difficult depending on the commodity (e.g. suppliers for raw agricultural commodities may be more difficult to identify than suppliers of manufactured ingredients).



Slide 12

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.



Slide 13

The supplier is the establishment that manufactures or processes the animal food, raises the animal, or grows the animal food without further manufacturing or processing by another establishment**.** This is true, even if the supplier and/or any intermediaries are exempt from all or portions of the *Preventive Controls for Animal Food* rule**.**

Slide 14

A supply-chain-applied control is used as a preventive control when the supplier controls the hazard in its ingredient or raw material before receipt of the ingredient or raw material by a receiving facility.

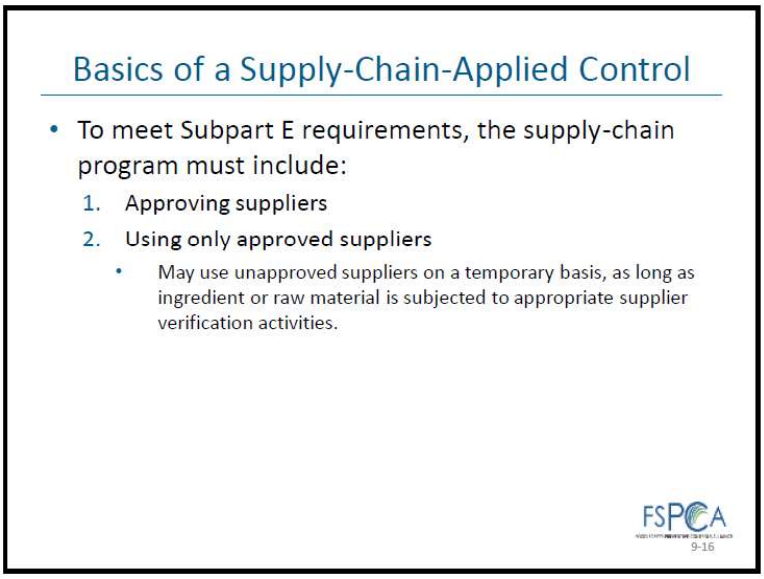
The receiving facility is ultimately responsible for implementing the supply-chain program and ensuring that hazards in the raw materials or other ingredients are controlled by the supplier.

The supply-chain program must be written (21 CFR 507.110) and would be considered part of the facility's Food Safety Plan (21 CFR 507.31(b)(3)).

Slide 15

To meet Subpart E requirements, the supply-chain program must include:

1. Approving suppliers
2. Using only approved suppliers
3. Having written receiving procedures that the receiving facility follows and documents to ensure they only receive raw materials or other ingredients from approved suppliers
4. Determining, conducting, and documenting appropriate supplier verification activities
5. Implementing appropriate preventive control management components to ensure effectiveness of supply-chain applied control
6. Documentation to meet the recordkeeping requirements associated with the supply-chain program



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

The requirement for a receiving facility to "approve suppliers" may make supply-chain applied controls more challenging for animal food manufacturing facilities to implement compared to other preventive controls because bulk animal food is often supplied through brokers and distributors.

Slide 16

The receiving facility is the sole entity that can approve suppliers. Before receiving a raw material or other ingredient that requires a Supply-Chain-Applied Control, the receiving facility must approve the supplier and document the approval. While there is flexibility given to performing other components of the supply-chain program, only the receiving facility can approve suppliers.

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.

Once the receiving facility has approved suppliers, they must take measures to ensure they only use raw materials and other ingredients from their approved suppliers. Using only approved suppliers ensures that the receiving facility only receives material from an entity that it has verified can control the hazard requiring a preventive control.

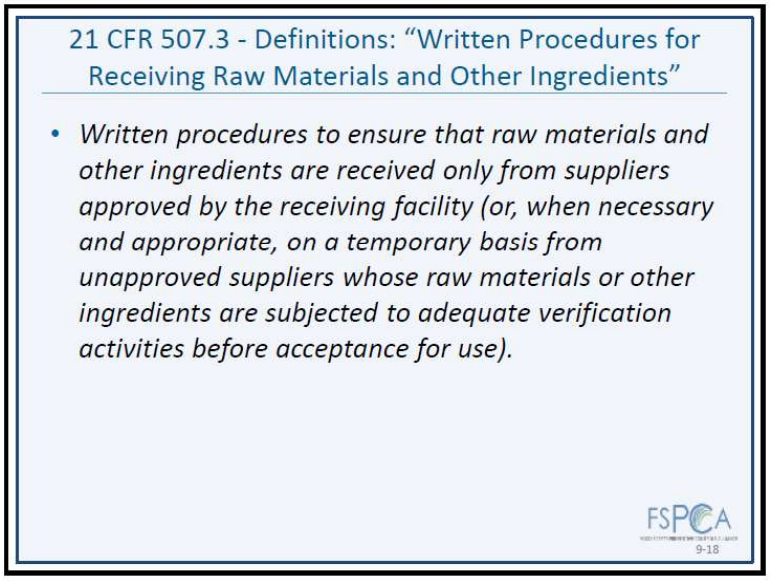
However, it is realistic to assume that there will be times when an ingredient is needed, but no approved supplier is able to provide it. Understanding this possibility, the rule allows, on a temporary basis, for the receiving facility to receive an ingredient from an unapproved supplier. In these cases,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

Slide 17

To ensure that the receiving facility only uses ingredients from an approved supplier, the receiving facility must have written procedures for receiving raw materials and other ingredients (see definition on slide 9-18), ensure these procedures are being followed, and document they are being followed.

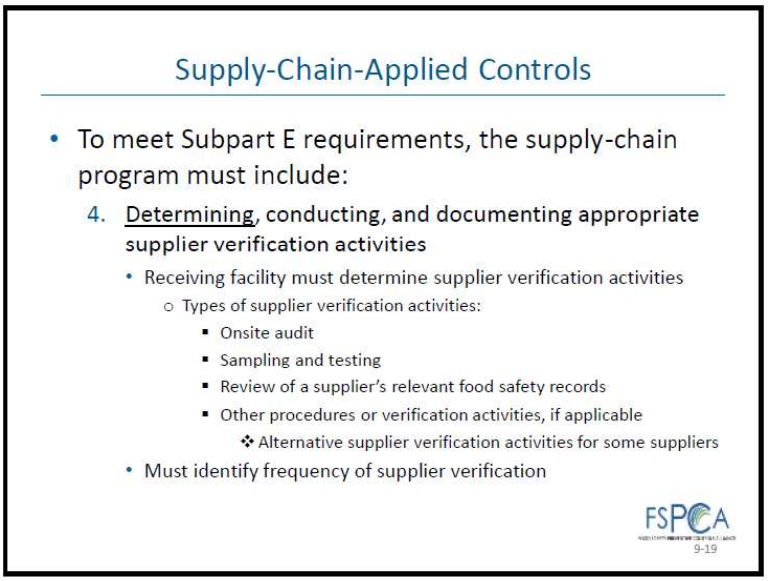
The receiving facility has flexibility to design appropriate written procedures for receiving raw materials and other ingredients that are tailored to their facility and operations. The goal of these written procedures is to ensure that they can accurately identify approved suppliers and incorporate changes to suppliers in a timely and accurate way. These written procedures allow consistent implementation of the supply-chain program by personnel who order raw materials and other ingredients, personnel who receive raw materials and other ingredients, and personnel who conduct supplier verification activities.

The receiving facility is responsible for ensuring that the supply-chain program has these written procedures developed, that the procedures are being implemented, and that there is documentation to show that procedures are being followed. The receiving facility may choose to take on this responsibility itself, or the receiving facility can rely on another entity (such as a broker or distributor) to conduct these activities. If the receiving facility relies on another entity to conduct this activity, they must review the documentation (and document the review) to verify that the written procedures are being followed.



Slide 18

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).*"



Slide 19

Once approved suppliers are identified and receiving procedures written, 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 receiving facility must determine one or more of the following verification activities that must be conducted before initial use of the raw material or ingredient and periodically thereafter.

- Onsite audit (See slide 9-23)
- Sampling and testing (See slide 9-25)
- Review of the supplier's relevant food safety records, such as the Food Safety Plan or processing temperatures (See slide 9-26)
- Other verification activities deemed appropriate based on the risk associated with the ingredient and the supplier (See slide 9-26)
    - The rule provides for alternate supplier verification activities if the supplier is one of three types of entities. If a supplier is a Qualified Facility, a small produce farm, or shell egg producer with less than 3,000 laying hens, the alternate supplier verification activities are limited and involve obtaining certain attestations. These circumstances are described in 21 CFR 507.110.

In addition to determining the appropriate types of supplier verification activities, the receiving facility must also determine the frequency that the verification activities need to be conducted. There are several factors that must be taken into consideration when determination what is an appropriate supplier verification activity (see slide 9-22).

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.

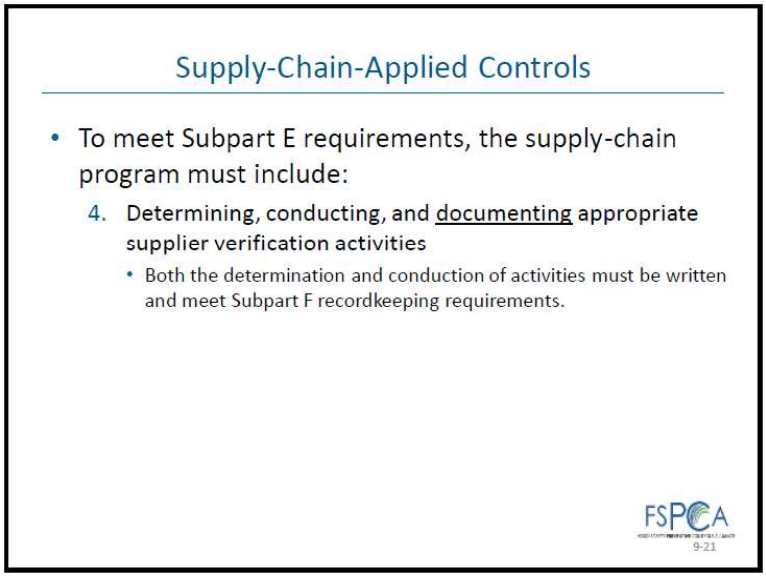
Slide 20

Once the facility has identified the appropriate types and frequency of verification activities, they are responsible for making sure these activities are conducted. A receiving facility can conduct these activities themselves. However, a receiving facility can instead rely on another entity, such as a broker or distributor, to determine the appropriate supplier verification activity and/or conduct supplier verification activities provided that the receiving facility reviews and assesses the entity's applicable documentation.

While a receiving facility can rely on another entity to determine and conduct supplier verification activities; there are restrictions on what suppliers can do for the receiving facility. 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. 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. Sampling and testing is the only supplier verification activity a supplier can conduct for the receiving facility, provided the receiving facility has determined that this is an appropriate verification activity for that animal food.

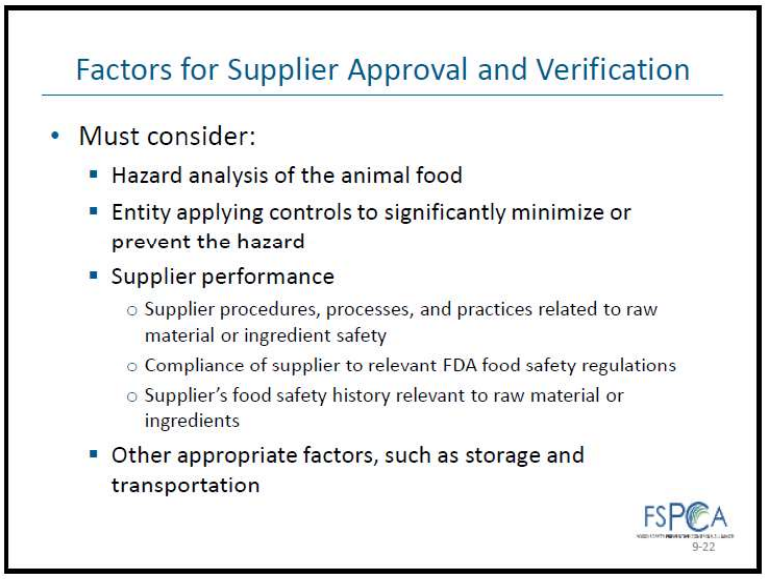
Regardless of the type of verification activity, it must be completed before using the raw material or other ingredients, and periodically thereafter.

Ultimately, it is the responsibility of the receiving facility to ensure that the Supply-Chain Program provides assurance that a hazard requiring a preventive control has been significantly minimized or prevented.



Slide 21

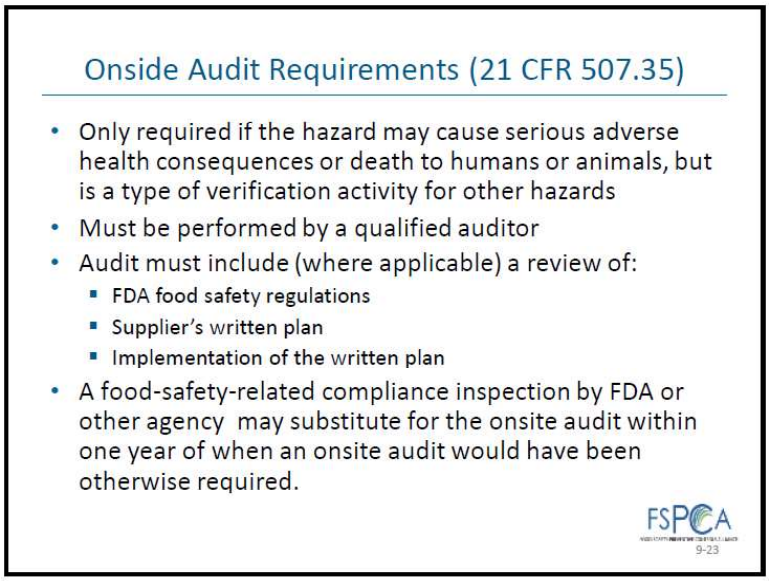
Finally, the activities associated with both the determination and conduction of the supply-chain program must be written. As with all records that support the Food Safety Plan, they must meet the recordkeeping requirements set out in Subpart F.



Slide 22

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 specific entity applying the controls
- The supplier's performance, such as procedures, processes, and practices related to food safety, compliance with applicable FDA food safety regulations, and food safety history
- Other factors, as appropriate and necessary, such as the storage and transportation of the raw materials or ingredients



Slide 23

There is not a requirement for an annual onsite audit except when the hazard is a SAHCODHA hazard (a PCQI may provide written a written determination that other activities and/or less frequent auditing is adequate for the SAHCODHA).

Any audit conducted under the supplier verification program must be conducted by a qualified auditor (defined on slide 9-24). Audits include both records review and observation of practices. A comprehensive systems audit that includes records review is 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.

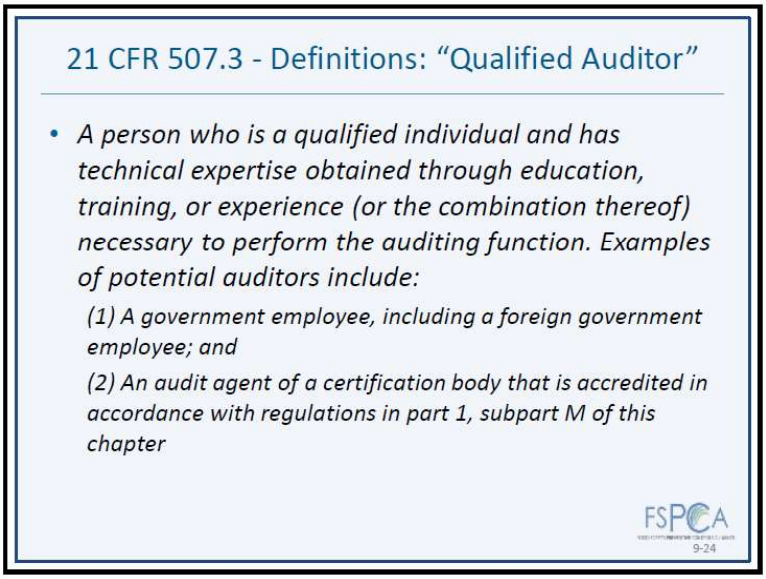
The audit must address process, sanitation, and supply-chain-applied controls, as well as CGMPs, as applicable. In addition, the audit must address, where applicable, relevant FDA food safety regulations, the supplier's written plan, and the implementation of the written plan. Lastly, the audit must 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.

SAHCODHA hazards are hazards for which there is a "reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals." See chapter 3 for additional discussion on SAHCODHA hazards.

For a SAHCODHA hazard, the audit must be conducted before receiving an ingredient and at least annually thereafter.

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.



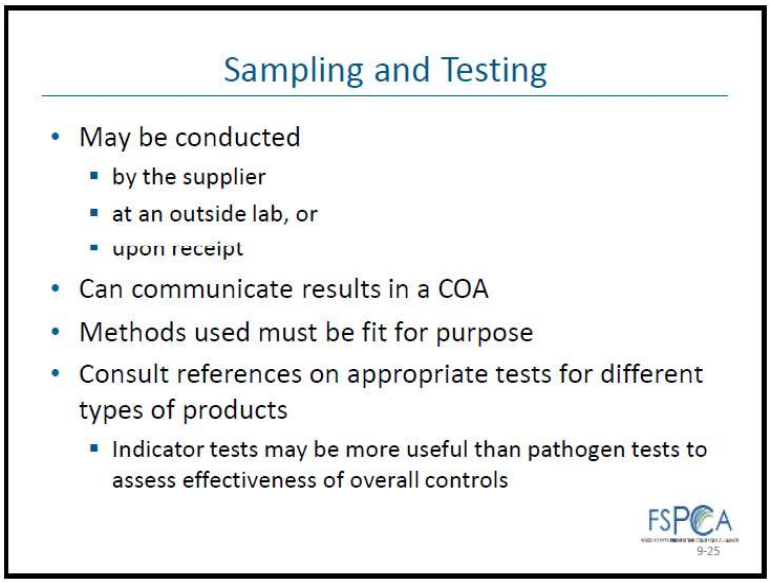
The "part 1, subpart M" referred to in this definition is the Accredited Third-Party Certification rule.

Slide 24

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

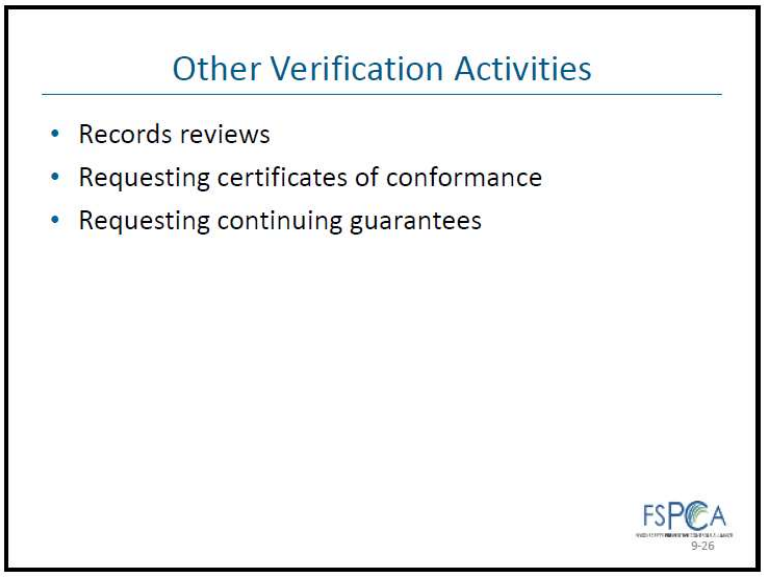
(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter"



Slide 25

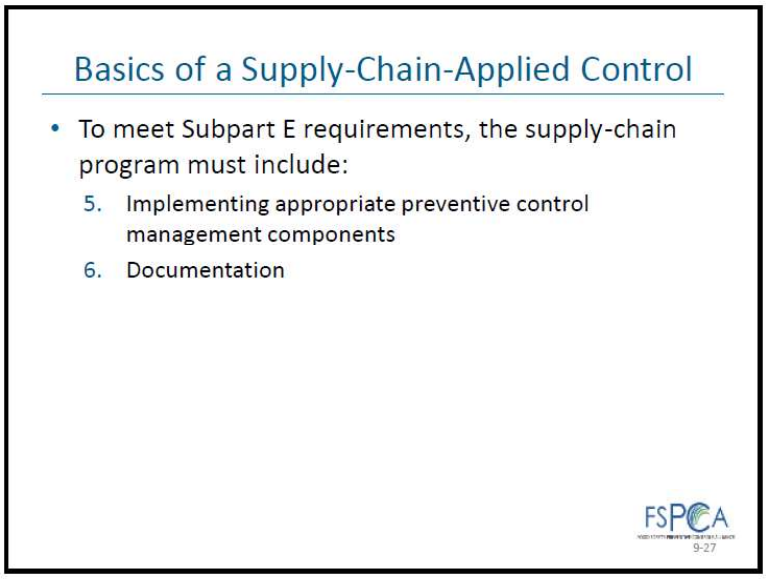
Testing of in-process materials, environmental samples, or the ingredient produced by the supplier may be appropriate as a verification activity if such testing provides meaningful results related to control of a hazard requiring a preventive control. Testing can occur at the supplier's facility, at 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.



Slide 26

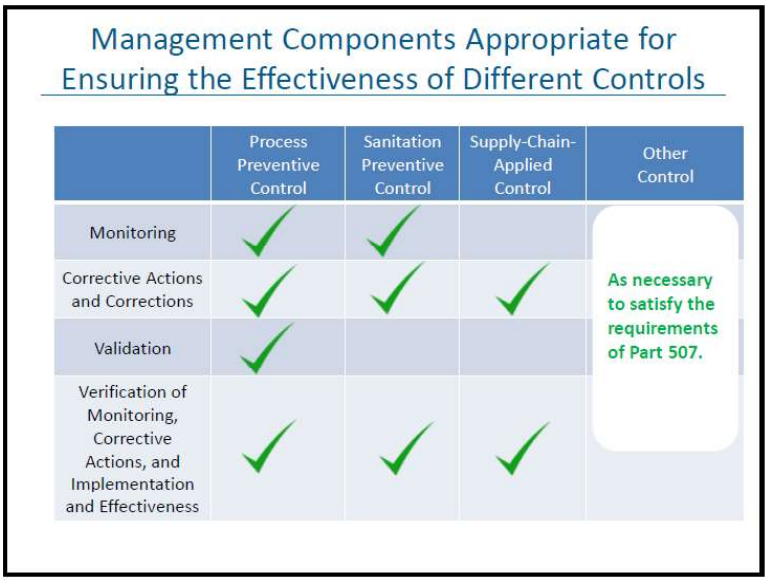
The PCQI may determine that other activities may be useful for supplier approval and verification depending on the hazards being managed. Companies may require their vendors to provide a Continuing Product Guarantee certifying that the product meets company requirements, including legal, regulatory, 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.



Slide 27

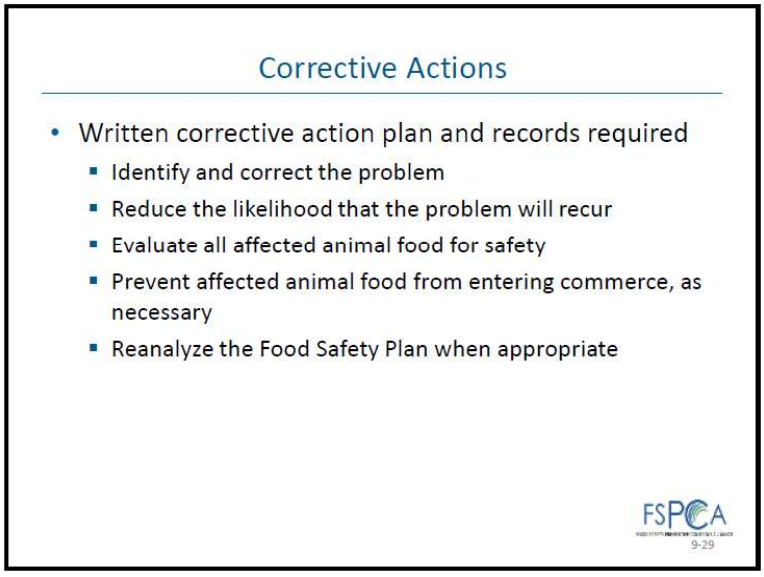
The receiving facility must implement appropriate preventive control management components to ensure a supply-chain-applied control is effective in controlling an identified hazard. The preventive control management components for a supply-chain applied control should be appropriate for the hazard. (See slide 9-20)

There are numerous documentation requirements associated with the supply-chain program in the rule. (See slide 9-30)



Slide 28

Preventive control management components were introduced in Chapter 6. As noted in 21 CFR 507.39, found on page 56347 of Appendix I, the Supply-Chain Program is subject to corrective actions and corrections and verification of implementation and effectiveness, specifically including a review of records of calibration, testing, and supplier and supply-chain verification activities. The use of the preventive control management components for a Supply-Chain Program should be as appropriate to ensure the effectiveness of the Supply-Chain Program and take into account the nature of the hazard controlled before receipt of the ingredient.

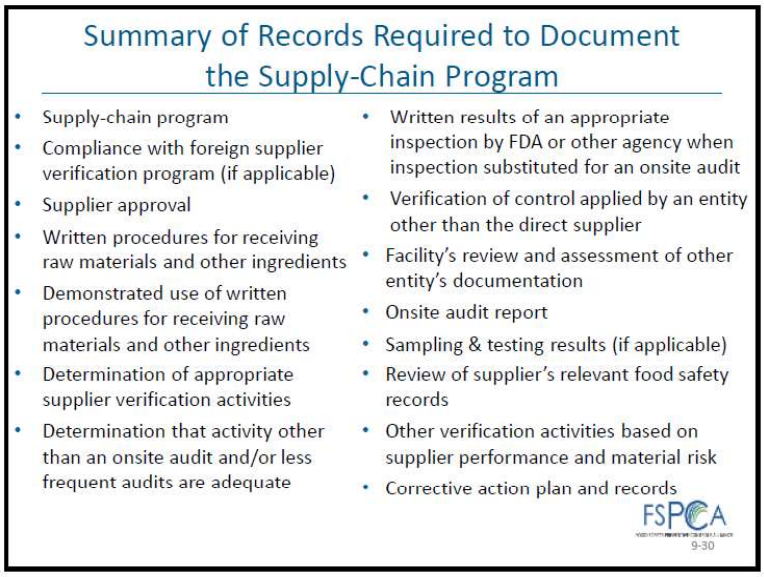


Slide 29

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).



Slide 30

This slide is a summary of the key required documents for the supply-chain program, if applicable, to the facility's program. Without records, one cannot demonstrate supplier programs are implemented as designed and are effective in controlling hazards.

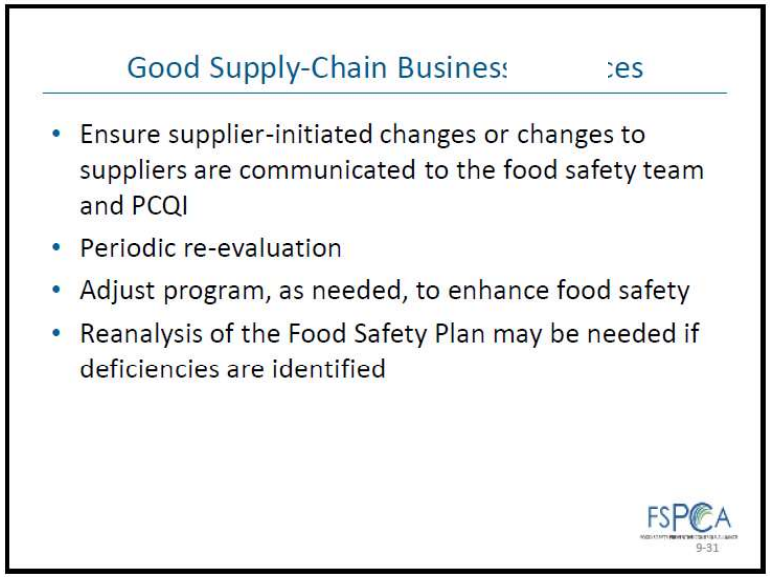
The documentation requirements start with the written Supply-Chain Program or documentation of compliance with the foreign supplier verification program (if applicable).

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. If verification activities other than those above are used, they must also be documented. Corrective actions, if any, must also be documented in response to the detection of hazards through sampling and testing.

Not all of these documents will be required for every facility's supply-chain program. If a facility does not include a component in their supply-chain program, such as onsite audits, the facility would not be required to maintain records associated with the onsite audit.



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.

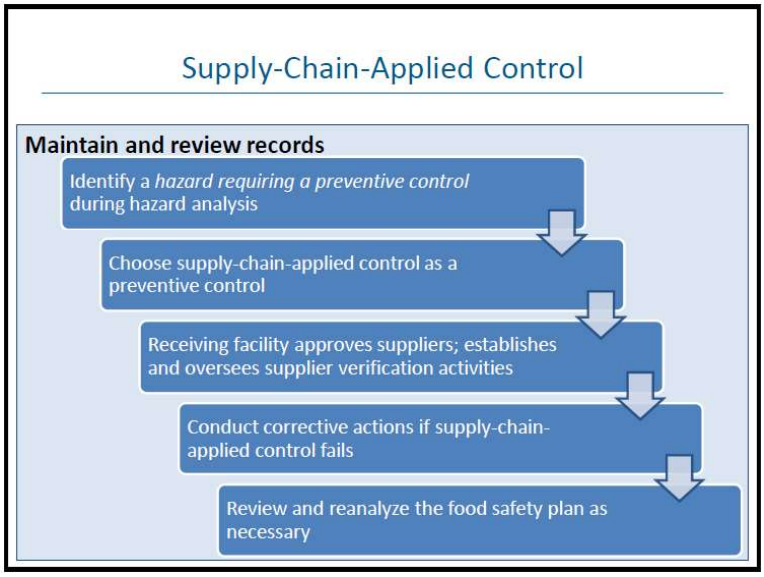
Slide 31

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.

It is a good business practice to evaluate the supply-chain program on a routine basis (typically annually) as suppliers may change their processes, your facility may create new formulations, or new hazards may arise. 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.

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.

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. Reanalysis of the Food Safety Plan may be required if there is an identified failure of a supply-chain applied control.

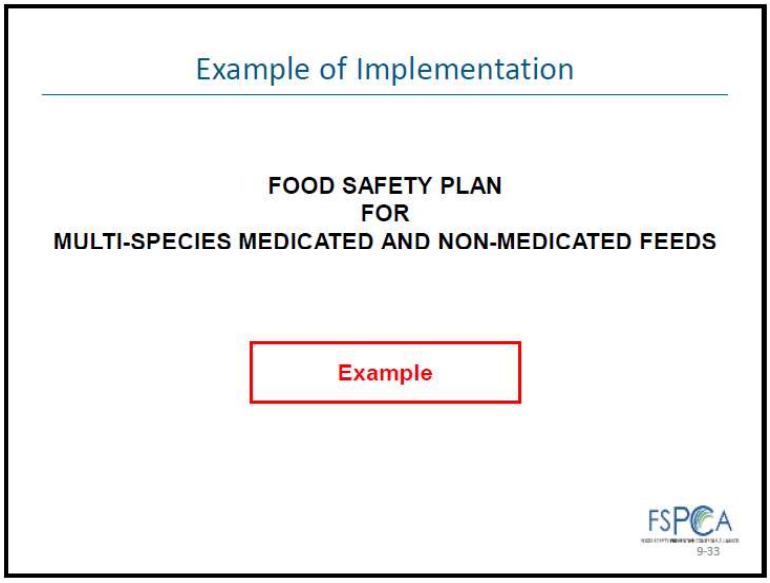


Slide 32

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.

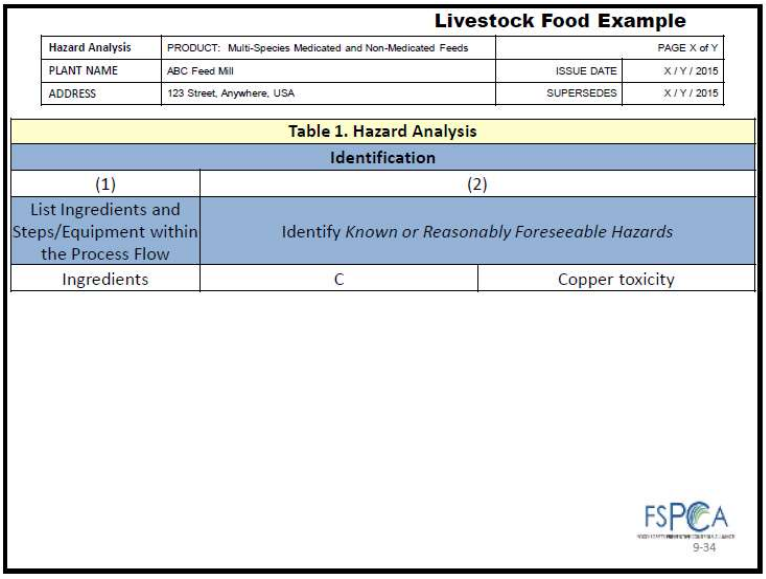
For all of these actions, records must be generated, maintained, and reviewed in accordance with requirements established in the *Preventive Controls for Animal Food* rule.



Slide 33

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

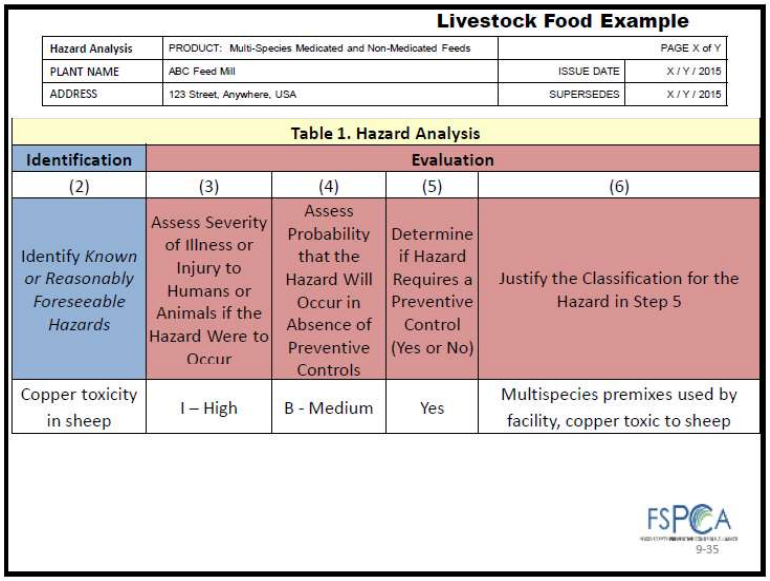
Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	C	Copper toxicity

FSPCA

9-34

Slide 34

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

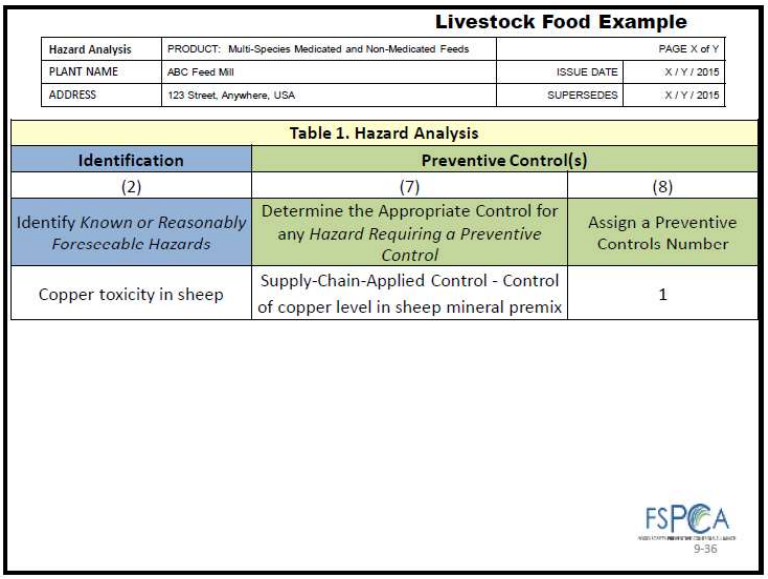
Table 1. Hazard Analysis

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

FSPCA 9-35

Slide 35

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

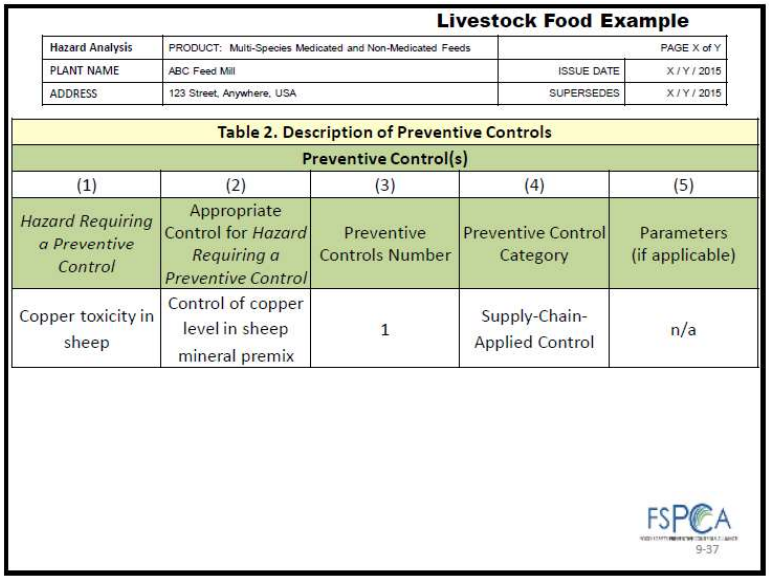
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Copper toxicity in sheep	Supply-Chain-Applied Control - Control of copper level in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

FSPCA

9-36

Slide 36

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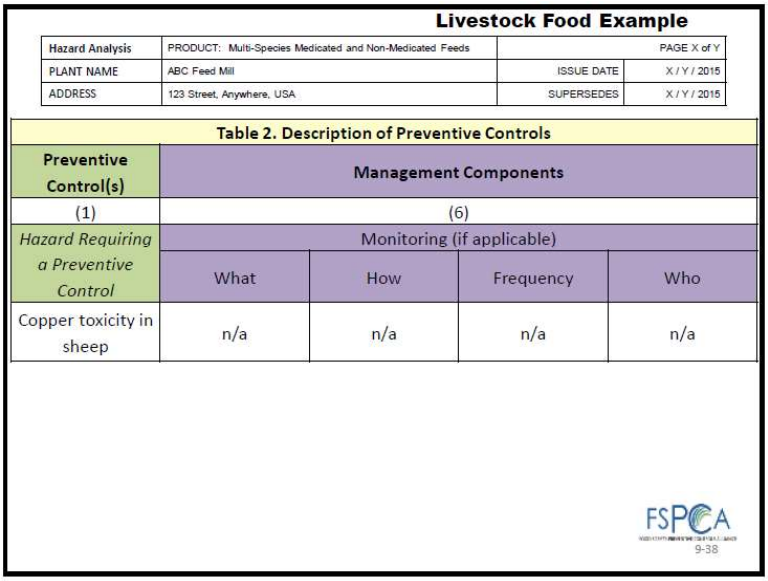
Table 2 identifies the preventive control category as being a Supply-Chain-Applied Control. There are no parameters (minimum or maximum values) associated with Supply-Chain-Applied Controls because the control is applied at the supplier and not at the facility, Thus, 'n/a' for 'not applicable' is placed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

FSPCA

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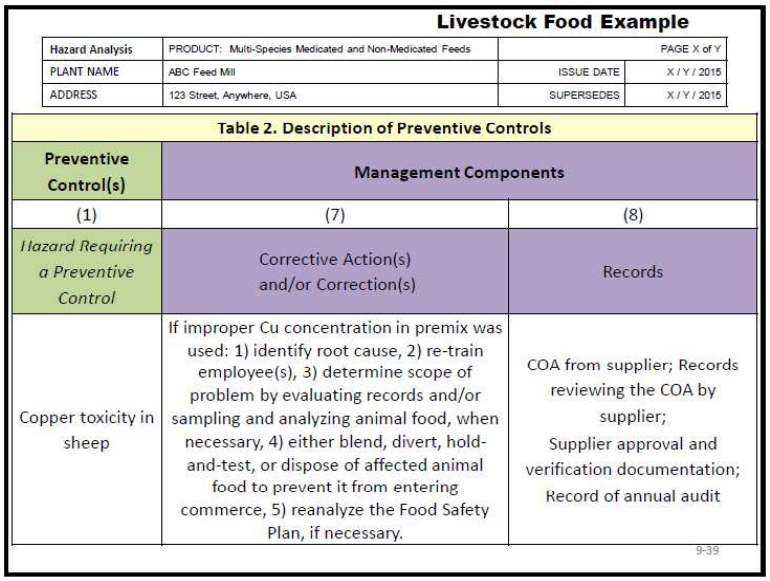
The monitoring row has n/a for not applicable because this example is for the receiving facility. Monitoring is not a required management component for receiving facilities if controlling a hazard through a supply-chain applied control. Instead, the monitoring is conducted by the supplier.

Slide 38

Supply-Chain-Applied Controls are not 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

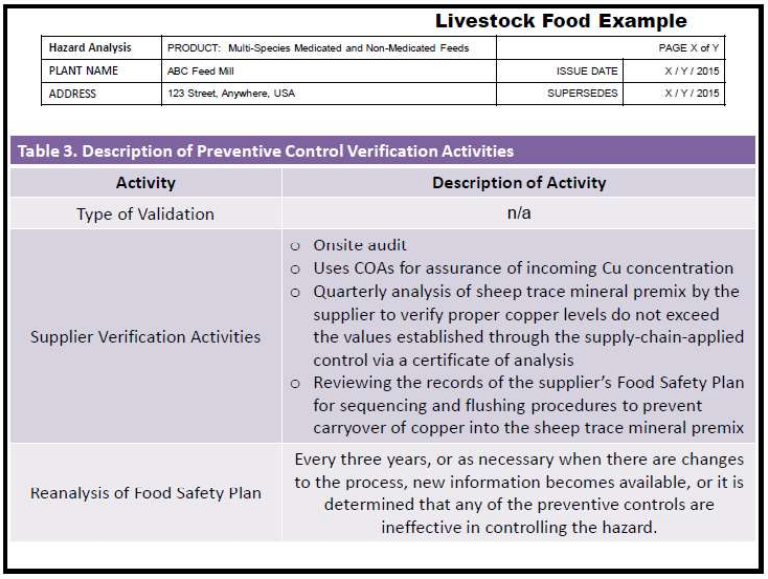
Preventive Control(s)	Management Components	
(1)	(7)	(8)
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records
Copper toxicity in sheep	If improper Cu concentration in premix was used: 1) identify root cause, 2) re-train employee(s), 3) determine scope of problem by evaluating records and/or sampling and analyzing animal food, when necessary, 4) either blend, divert, hold-and-test, or dispose of affected animal food to prevent it from entering commerce, 5) reanalyze the Food Safety Plan, if necessary.	COA from supplier; Records reviewing the COA by supplier; Supplier approval and verification documentation; Record of annual audit

9-39

Slide 39

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

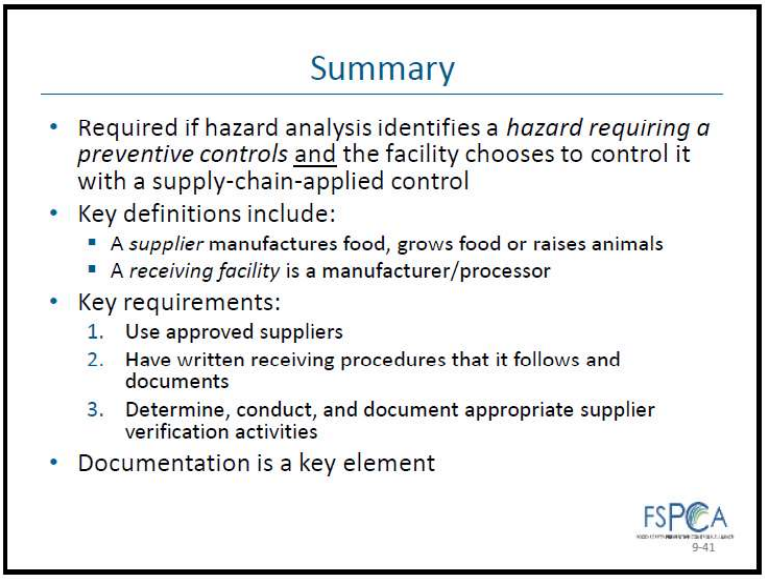
Activity	Description of Activity
Type of Validation	n/a
Supplier Verification Activities	○ Onsite audit ○ Uses COAs for assurance of incoming Cu concentration ○ Quarterly analysis of sheep trace mineral premix by the supplier to verify proper copper levels do not exceed the values established through 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.

Slide 40

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 value 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.



Slide 41

In summary, 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, grows the food, or raises the animal that the receiving facility uses to make the product. There are key requirements that must be met if a receiving facility uses a supply-chain control to control a hazard, such as:

- Approving suppliers,
- Using approved suppliers,
- Having and using written procedures to ensure ingredients are only received from approved suppliers
- Conducting and documenting supplier verification activities
- Documentation.

NOTES

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