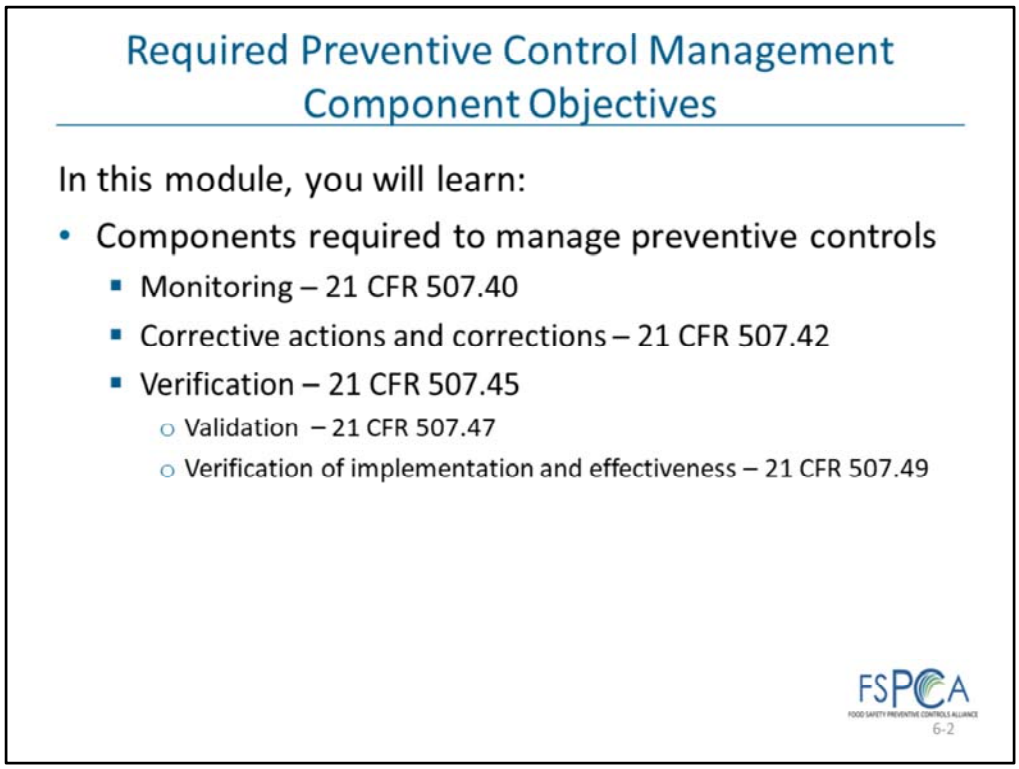
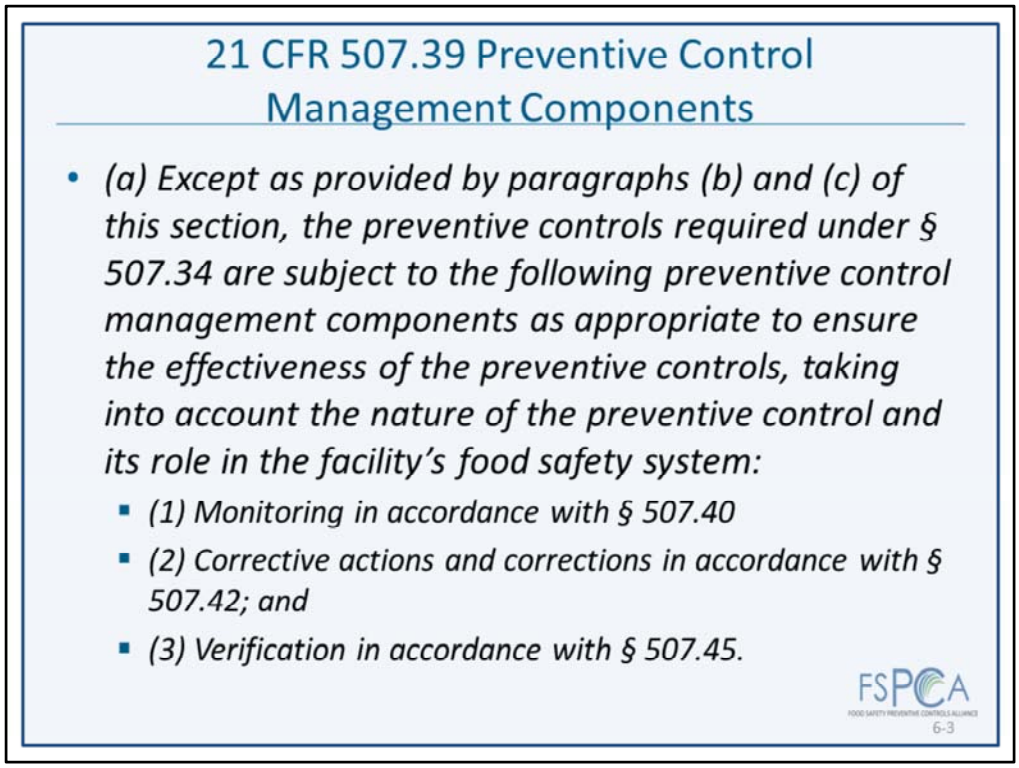
While the previous chapter helped describe the process for conducting the hazard analysis and determining which hazards require a preventive control, this chapter will discuss the required management components for those preventive controls so they are effective. The preventive control management components are listed in 21 CFR 507.39, which can be found on page 56347 of Appendix I. This chapter refers to multiple sections of the regulatory text, so it is important to follow along in the Preventive Controls for Animal Food rule. For example the section on verification requirements is 21 CFR 507.45, but that section also refers other requirements in 21 CFR 507.47, 507.49, and 507.55.

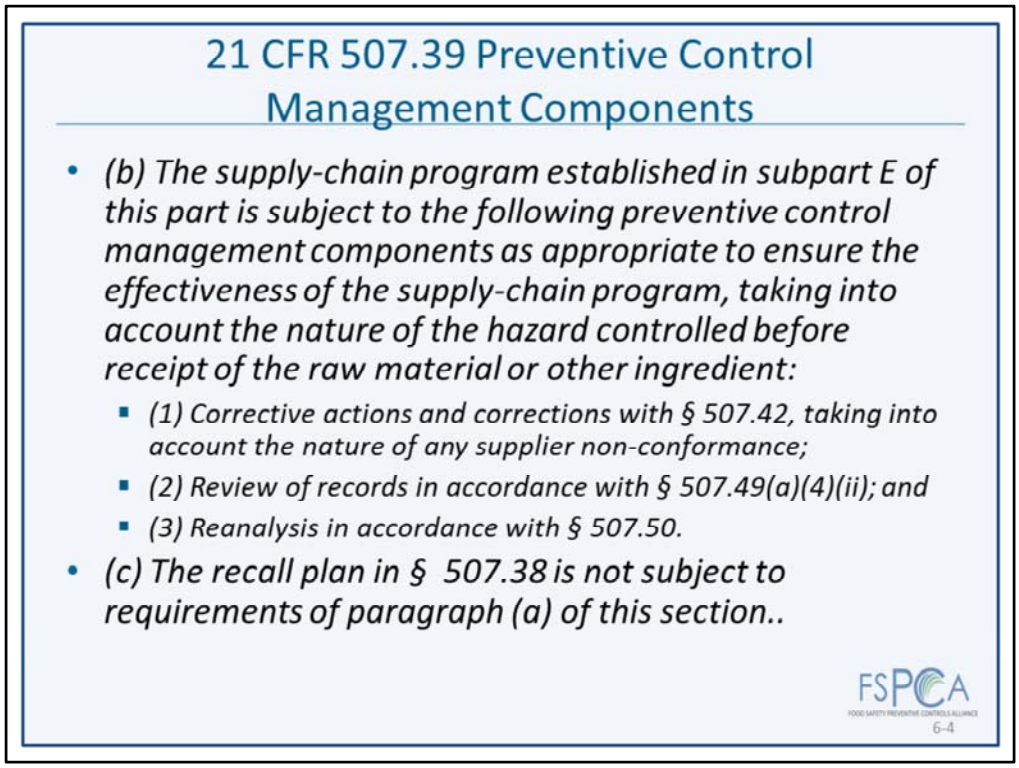


In this chapter, participants will learn the requirements for monitoring, taking corrective actions or corrections, and verification. Verification includes the concepts of validation and verification of implementation and effectiveness of the food safety plan. The preventive control examples from the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds will be used as an example in this chapter to illustrate the concepts and outline the required preventive control management components.

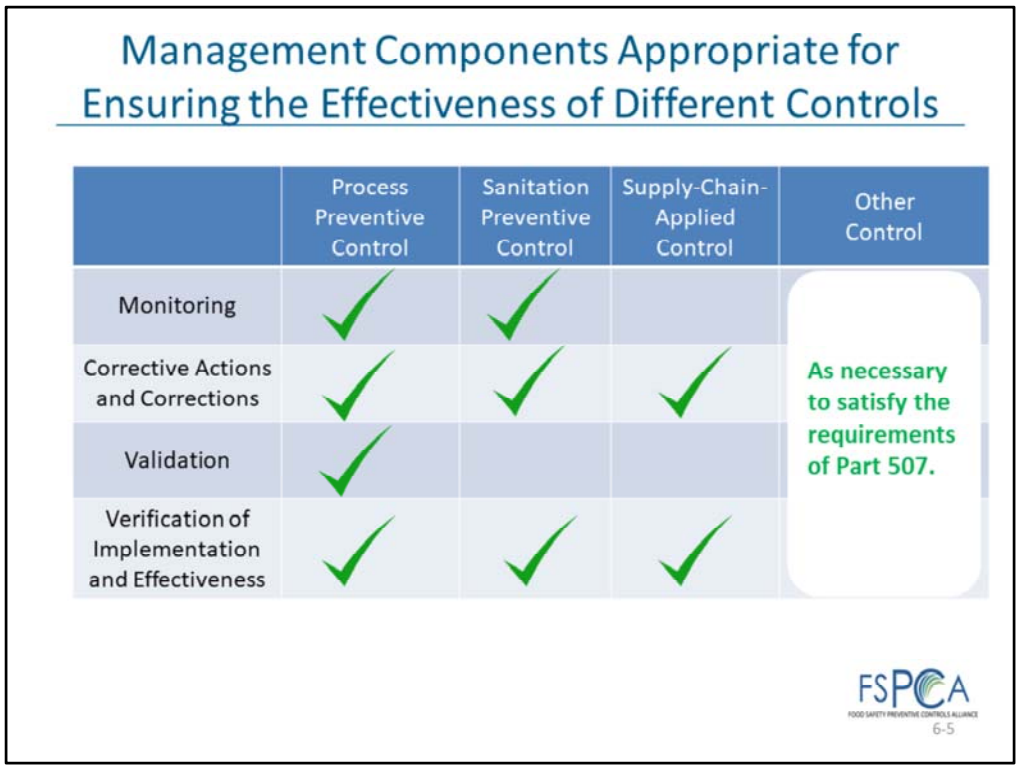


(The concepts of how facilities may apply these management components are explained in detail throughout the rest of the curriculum, particularly in Ch. 7, 8, and 9.)

The rule requires that a hazard requiring a preventive control have components to manage the preventive control. Those management activities include monitoring the preventive control as required by 21 CFR 507.40, corrective actions and corrections as required by 21 CFR 507.42, and verification as required by 21 CFR 507.45. The associated definitions and requirements of these activities will be introduced in this chapter, with more details for application provided in subsequent chapters.



This is the remainder of the regulatory text for 21 CFR 507.39. The balance of the chapter will explore the requirements in more depth. The supply-chain program does have required management components, but they are not clearly called out in this section. Those management components are described more fully in Subpart E and will be described in Chapter 9: Supply-Chain-Applied Controls.



(Reanalysis of the food safety plan and a Recall Plan are also required, and are described in Chapters 4, and 10, respectively)

This table is a summary of the preventive control management components that are required to ensure the effectiveness of different types of preventive controls.

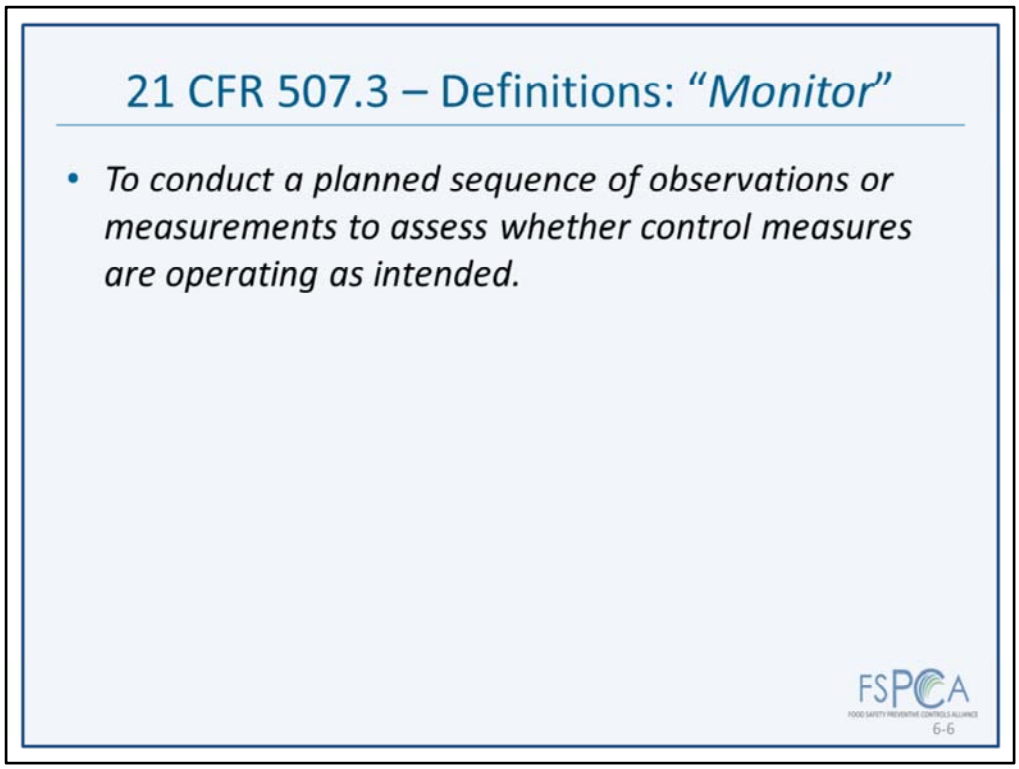
Process preventive control: The management components for process preventive controls are listed first. These components are described in more depth in Chapter 7. The required preventive control management components are monitoring, corrective actions and corrections, validation, and verification of implementation and effectiveness.

Sanitation preventive control: The next column lists the management components for sanitation preventive controls. Examples of these management components are described in more depth in Chapter 8. The required components are monitoring, corrective actions and corrections, and verification of implementation and effectiveness. Validation is not required for sanitation preventive controls.

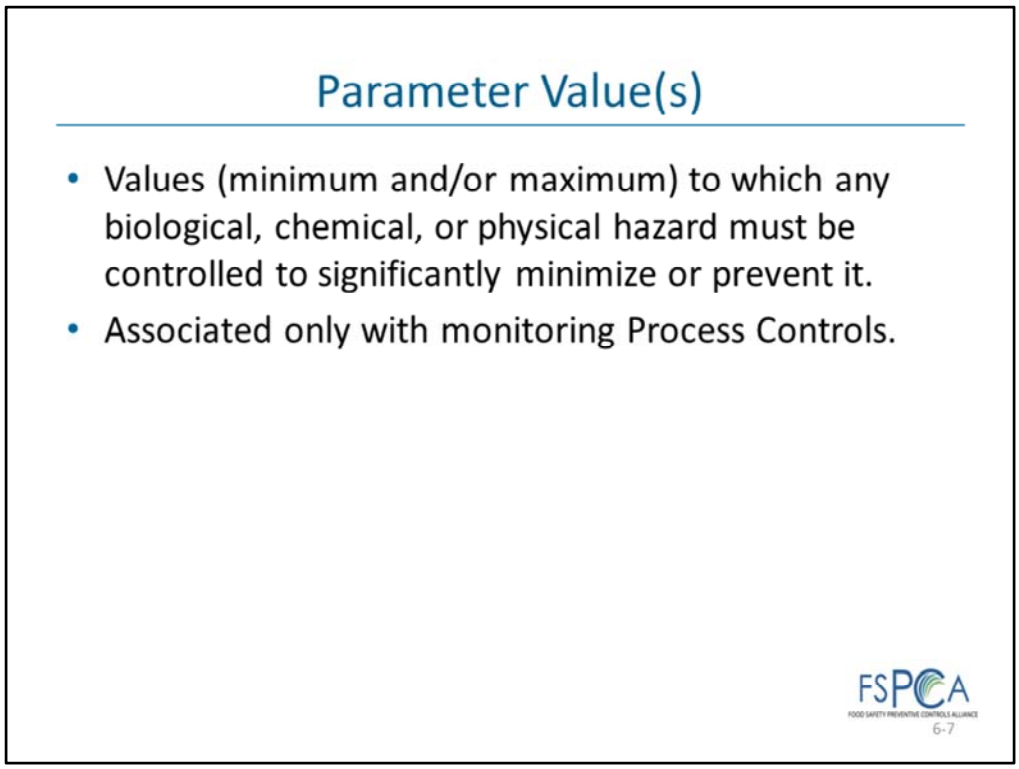
Supply-chain-applied preventive control: The management components for supply-chain-applied controls are listed in column three. The specific examples of these management components are covered in Chapter 9. The only management component required by 21 CFR 507.39 for supply-chain applied controls is review of records. However, the Supply-Chain Program in Subpart E describes the requirements for the other management components, such as corrective actions taken in response to significant deficiencies

identified during an audit or documentation of sampling and testing conducted as a supplier verification activity.

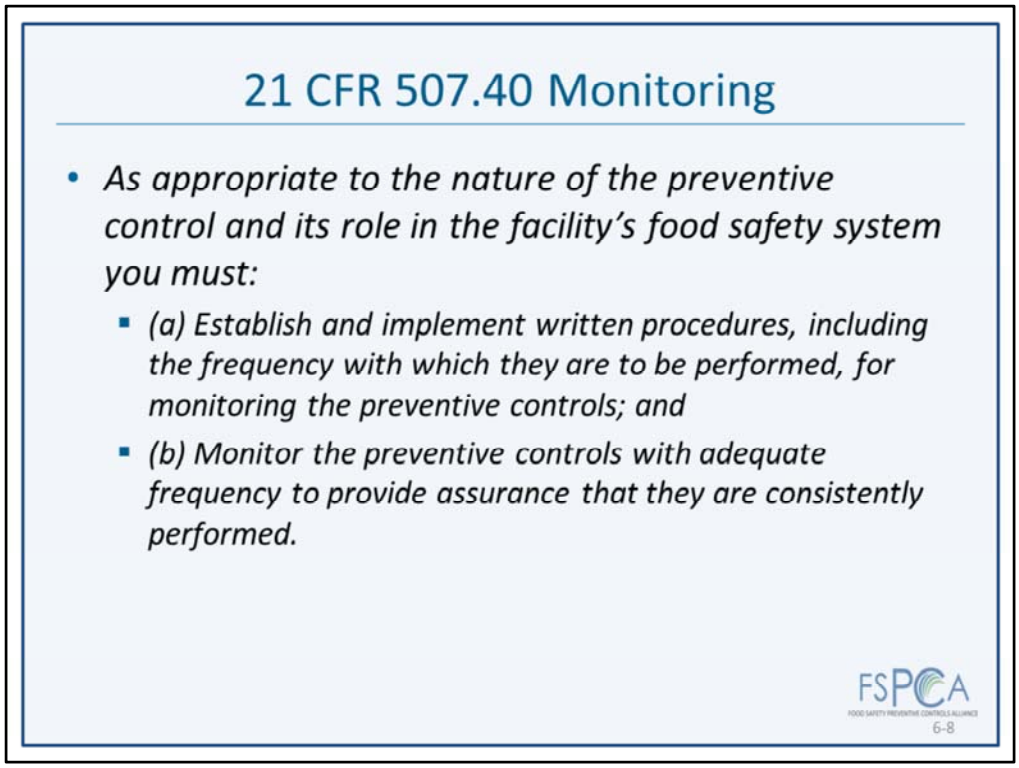
Other preventive control: Other preventive controls include procedures, practices, and processes as necessary to meet the requirements of part 507. Examples may include hygiene training and other current good manufacturing practices. The preventive control management components for “other controls” will depend on the nature of the control and the hazard it is controlling.



The first required preventive control management component is monitoring. The definition of monitor is *"to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended."*
In essence, monitoring involves the selection of appropriate measurements or observations at a specified frequency to provide information that is used to evaluate if a preventive control is meeting the parameters, such as a minimum or maximum value, that were set.

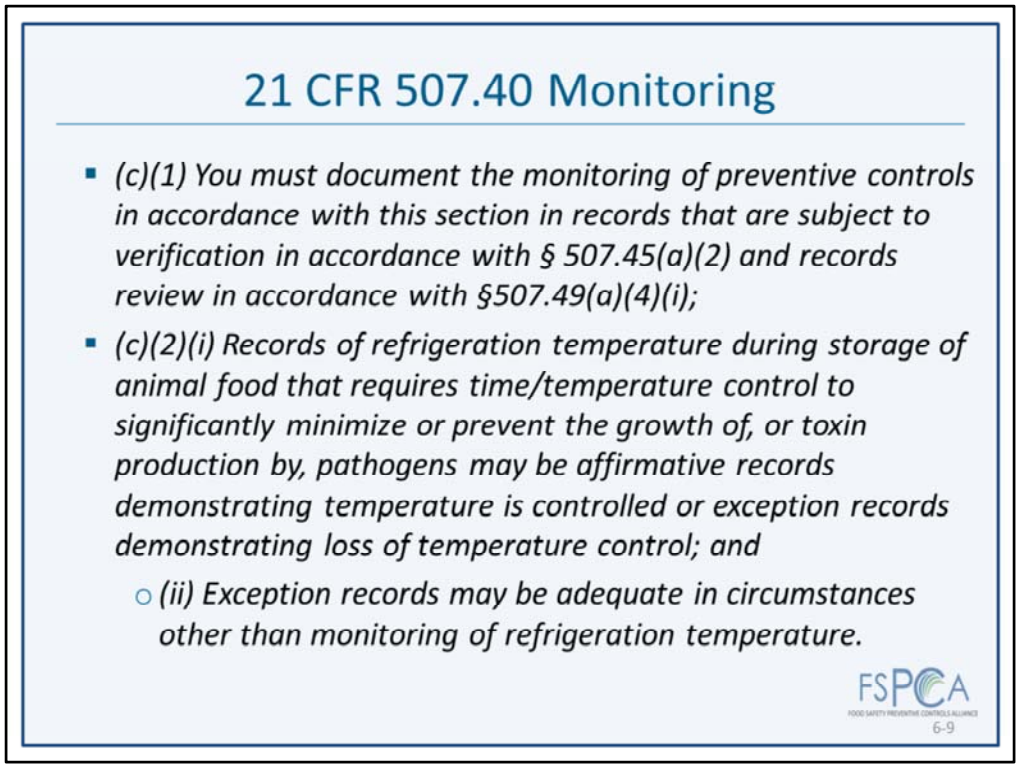


In order to monitor, some preventive controls require parameter values. Parameter values will be discussed more fully in Chapter 7, but they are minimum and/or maximum values to which any biological, chemical, or physical hazard must be controlled to significantly minimize or prevent it. Parameter values are associated only with process controls.



(A reminder: monitoring is only a required management component for process controls and sanitation controls, not supply-chain applied controls because the monitoring occurs at the supplier's facility. This is described in Ch. 9.)

Monitoring is required for process preventive controls and sanitation preventive controls. There is flexibility in how a facility can develop and design its monitoring system because conducting the activity may change as appropriate to the nature of the preventive control and its role in the facility's food safety system. A facility must have and implement written procedures for monitoring. These procedures must include how frequently the monitoring will occur. Monitoring must be completed on a frequent enough basis to ensure the preventive control is consistently working.



The monitoring of preventive controls must be documented. Records associated with that monitoring are subject to the recordkeeping requirements of Subpart F, which was discussed in Chapter 1. In facilities that produce food for livestock animals, examples of these documents may include daily production records. Daily production records may be sufficient to meet the requirements of a monitoring record. Additional monitoring requirements are required for facilities that use cold storage or refrigeration to ensure that microbial growth is controlled. For example, a facility using cold storage would need to document the monitoring of the refrigeration temperature. Regardless of what is being monitored (such as daily production records or temperature), the monitoring activity is used to make sure the preventive control is working or detect a problem if the preventive control is not working.

ABC Feed Mill **Livestock Feed Example**
123 Street, Anywhere, USA

SOP 200.6: Batching and Mixing – PC #2

Purpose: Proper batching and mixing of ingredients is important to ensure accurate and consistent nutrient delivery to animals and prevent negative impacts on animal food safety.
Frequency: Each run of feed
Who: Batching operator
Procedure:

1. Prior to manufacturing feed, check scales are zeroed and mixer is empty per scale readout.
2. Confirm the feed to be manufactured is appropriate based on the sequencing plan.
    a. Prior to manufacturing sheep feed, a complete feed that does not contain a high copper premix must be manufactured, and a flush must be run prior to batching.
3. Confirm the formula to be batched is accurate based on the master record formula.
4. Weigh all ingredients during batching, document, record lot numbers where appropriate.
5. Mix for 90 s dry mix and 120 s wet mix times for total of 210 s.
6. Discharge the mixer to the correct finished feed bin, following appropriate sequencing.

Monitoring: Quantity of ingredient weighed during batching of each run, daily reconciliation of the following ingredients: sheep trace mineral premix, beef trace mineral premix, swine trace mineral premix, copper sulfate
Corrective Action: 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.
Records: Batching records, daily reconciliation records, corrective action records
Verification of Review: Within 7 working days unless written justification is provided

Now that we have described the requirements of monitoring, we will show an example of how a facility may choose to employ procedures to meet those requirements. The Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds will be used to illustrate the requirements of monitoring for the required preventive control. The example used throughout this chapter will be Preventive Control #2, the weighing and addition of sheep mineral premix to ensure its accurate addition. This preventive control helps ensure that the correct ingredient is used to manufacture the animal food and that the correct amount of ingredient is utilized.

This example standard operating procedure (SOP) outlines the required steps for manufacturing an animal food intended for sheep. These steps include 1) checking scales are zeroed and the mixer is clean, 2) ensuring the previous diet manufactured did not contain a high level of copper, and 3) confirming the formula is accurate according to the master record formula. After the preliminary steps are completed, 4) the ingredients are weighed and that weight recorded. Lot numbers of ingredients, where appropriate, are recorded during this step. The ingredients are 5) mixed, and then the animal food is 6) discharged from the mixer. Step number 4 (weighing all ingredients and recording the weight) is the preventive control used as an example in this chapter. The next few slides will discuss the monitoring of this preventive control to ensure it is completed appropriately.

Example of Batching Record

ABC Feed Mill
123 Street, Anywhere, USA
Master Formula Batch Sheet
Sheep Diet – Non-medicated

Date manufactured: 3-3-16

Ingredient	Amount Required	Amount Added	Lot #	Batch Operator
Corn	1808	1809	Bin #2	CS
Alfalfa meal	300	305	Bin #1	CS
Soybean hulls	300	297	Bin #5	CS
Soybean meal	360	353	Bin #8	CS
Wheat	120	113	Bin #4	CS
Urea	15	15	7198	CS
Ammonium Chloride	15	15	TA203	CS
Limestone	45	45	222016	CS
Sheep mineral premix	30	30	FS1237M	CS
Vitamin premix	7	7	KSMC1984	CS
Total	3000	2989	n/a	CS

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(Other monitoring records are needed to satisfy the other preventive controls for copper toxicity in the Example Food Safety Plan for Medicated and Non-Medicated Feeds. For example, Preventive Control #3 is the procedure for mixing and sequencing food for sheep to prevent toxic levels of copper from carryover from a previous animal food. For Preventive Control #3, monitoring would involve documenting the previous batch manufactured. Oftentimes, daily production records from automation systems are appropriate to use as monitoring records for that type of preventive control.)

In this example, monitoring Preventive Control #2 is accomplished by the reconciliation of designated ingredients. These include sheep mineral premix and ingredients that contain added copper, which for this facility include cattle mineral premix, swine mineral premix, and copper sulfate. The batch-to-batch and daily use of these four ingredients are reconciled to monitor the preventive control to ensure the correct volume of designated ingredients were used.

To accomplish the monitoring activity, the quantity of ingredient utilized will be recorded on batching records throughout the day. This slide presents an example of a batching sheet for an animal food intended for sheep. The quantity of sheep mineral premix added to each batch of animal food and the ingredient's lot number are recorded on the batching sheet. The batching operator, Chad Smith, has been assigned the responsibility for documenting the quantity of sheep mineral premix added to each batch and its lot number. The quantity and lot number of the sheep mineral premix is reconciled on a batch-to-batch basis to ensure the correct premix is used at the appropriate volume.

ABC Feed Mill **Livestock Feed Example**
123 Street, Anywhere, USA

SOP 200.9: Daily Reconciliation of Designated Ingredients – PC #2

Purpose: Reconciliation of theoretical and actual use of designated ingredients is necessary to ensure accurate and consistent nutrient delivery to animals and prevent negative impacts on animal food safety. Designated ingredients are: sheep trace mineral premix, beef trace mineral premix, swine trace mineral premix, copper sulfate.
Frequency: Part 1: Each run of feed; Part 2: Daily
Who: Batching operator
Procedure:

1. Throughout the day:
    a. Record the quantity and lot number of designated ingredients used, sold, spilled or otherwise disposed throughout the day.
    b. Evaluate discrepancies throughout the day and investigate when appropriate.
2. At the end of the production day:
    a. Calculate total quantity of all designated ingredients used, sold, spilled or otherwise disposed of throughout the day (theoretical use)
    b. Conduct an inventory of all designated ingredients, regardless if they were used (actual use)
    c. Compare the actual daily disappearance of each ingredient (based on beginning versus ending inventories) to the anticipated daily theoretical use
    d. Calculate the percent deviation between theoretical usage and actual disappearance of the ingredients
    e. Report any deviation greater than 10% to a supervisor and investigate.

Monitoring: Theoretical use vs. actual use deviation; parameter: must be within 10%
Corrective Action: 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
Records: Batching records, daily reconciliation records, corrective action records
Verification of Review: Daily by Supervisor, within 7 working days by PCQI unless justified in writing

An SOP specific to daily reconciliation of designated ingredients was developed by the facility as another level of assurance that the correct premix was used during manufacturing. This process outlines the steps that must be completed by the batching operator to determine the inventory of designated ingredients. The SOP outlines that the batching operator will record the quantity and lot number of designated ingredients used, sold, spilled, or otherwise disposed of throughout the day. This allows him or her to evaluate if each batch of animal food in a run had the correct volume of ingredient added.

At the end of the production day, regardless if the designated ingredients were used or not used, the batching operator uses the batching records to calculate the theoretical quantity of designated ingredients used during the day. He or she then conducts an inventory by weighing and/or counting remaining bags of the designated ingredient to calculate the actual use during that day. The batching operator then calculates the percent deviation between theoretical and actual disappearance.

The SOP identifies that the parameter has been set at 10% between theoretical and actual use, so a deviation between theoretical and actual use greater than 10% of the volume of the difference between theoretical and actual use must be reported to a supervisor and investigated for appropriate correction or corrective action. These records are reviewed daily by the supervisor, and the PCQI reviews them weekly.

Example of Designated Ingredient Reconciliation Record

ABC Feed Mill
123 Street, Anywhere, USA
Date: 3-3-16 **Copper Source Daily Reconciliation**

Ingredient	Lot #	Start (lb)	End (lb)	Actual Use (lb)	Theoretical Use (lb)	Deviation (%)
Cattle TM premix	CTM 456216	38	38	0	0.0	0%
Swine TM premix	STM 332016	29	27	2	1.9	5.3%
Sheep TM premix	FS125TM	133	102	31	30	3.3%
Copper sulfate	CS122015	45	45	0	0.0	0%

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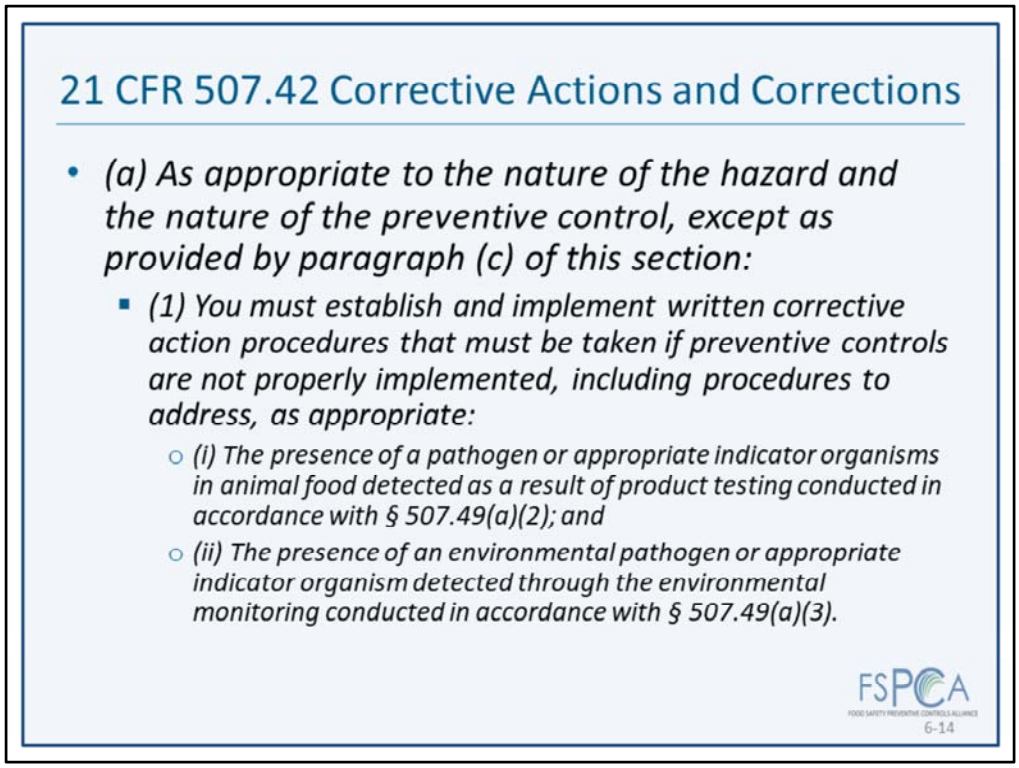
This is an example of a monitoring record that may be used in the determination of theoretical and actual use of designated ingredients. The first column lists the ingredients that must be reconciled daily. Next, there is a blank area for the lot number of the ingredients to be documented. The third column is the inventory of these ingredients at the start of the manufacturing process. This should be the same quantity that was the ending inventory from the previous manufacturing day. The fourth column is the ending inventory of the ingredients at the end of the current manufacturing day. The difference between the third and fourth column are utilized to determine the actual use based on inventory of the ingredients, and is in Column 5. Next, Column 6 is the sum of the theoretical quantity of each ingredients utilized throughout the day, which is calculated from the batching records. Finally in column 7, the deviation between the values is determined using the equation:

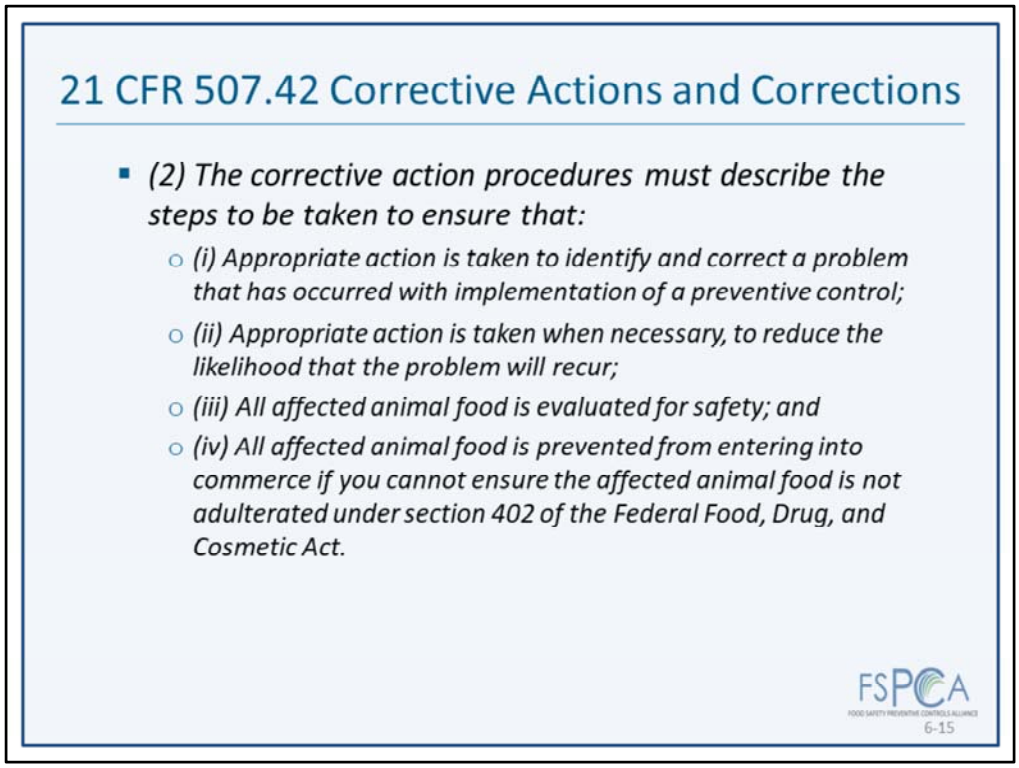
$$\text{Deviation} = \frac{(\text{actual use} - \text{theoretical use})}{\text{theoretical use}} \times 100$$

The SOP stipulates that any deviation greater than 10% between theoretical and actual use must be investigated. This monitoring record shows that all the designated ingredients were below this threshold.



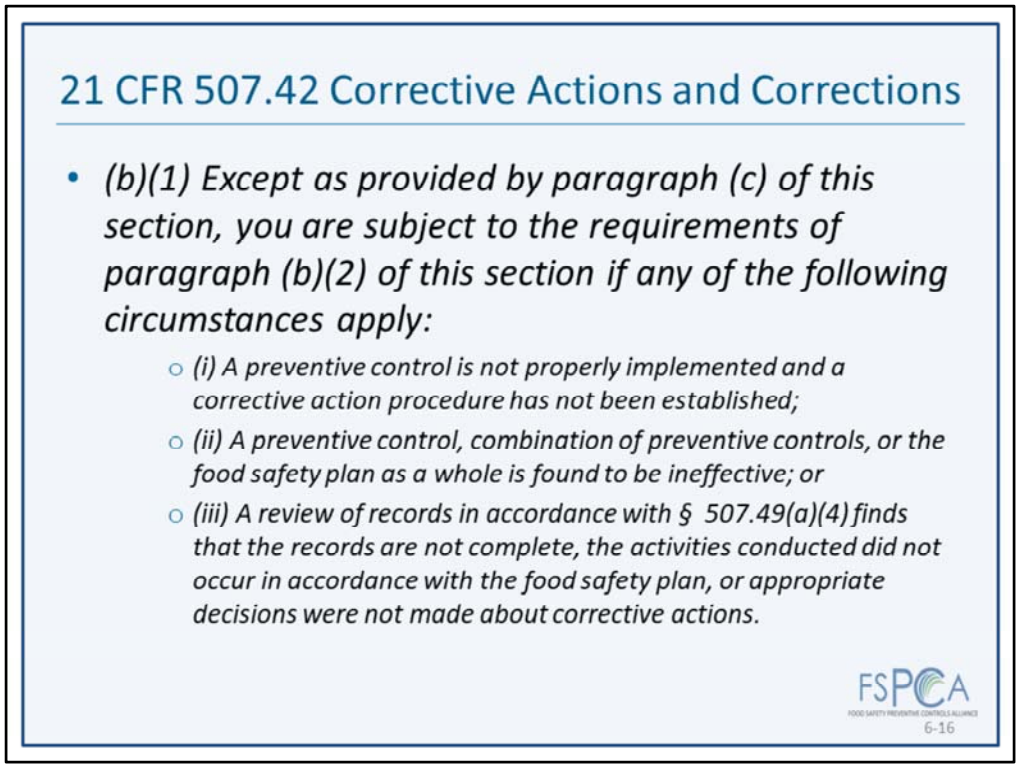
(A description of when it is appropriate to use correction as compared to corrective action is in Chapter 8: Sanitation Preventive Controls.)

If the deviation of one of the ingredients was greater than 10% in the previous example, a corrective action or correction may have been necessary. This leads to the second required preventive control management component, corrective actions and corrections. Requirements for corrective action and corrections apply to all types of preventive controls. The rule states that, as appropriate, the facility must establish and implement corrective action procedures that must be taken if preventive controls are not properly implemented or when a pathogen or environmental pathogen is found. Additional information related to the application of corrective actions and corrections for different types of preventive controls will be discussed in Chps 7, 8, and 9.



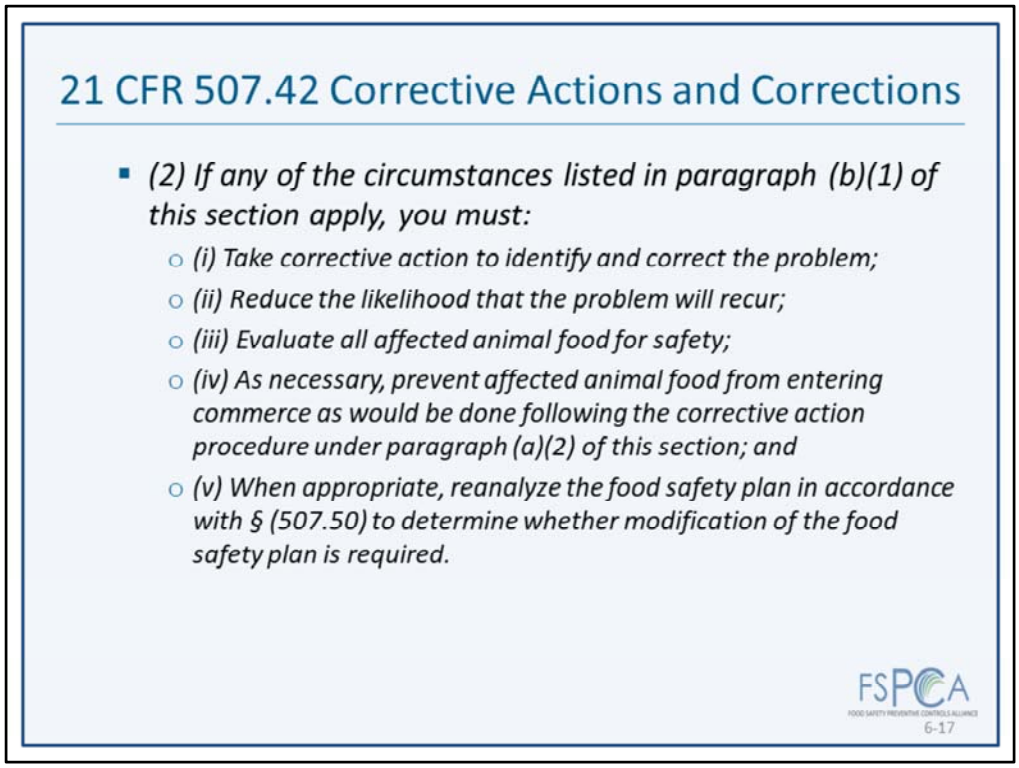
Corrective action procedures must be written and describe the corrective action procedures to ensure that:

- Appropriate action is taken to identify and correct a problem that occurred with the implementation of a preventive control,
- Appropriate action is taken when necessary to reduce the likelihood that the problem will reoccur,
- All animal food is evaluated for safety, and
- All affected animal food does not enter commerce if the facility cannot ensure its safety.



A facility must take corrective action in the event of an unanticipated animal food safety problem if any of the following circumstances apply:

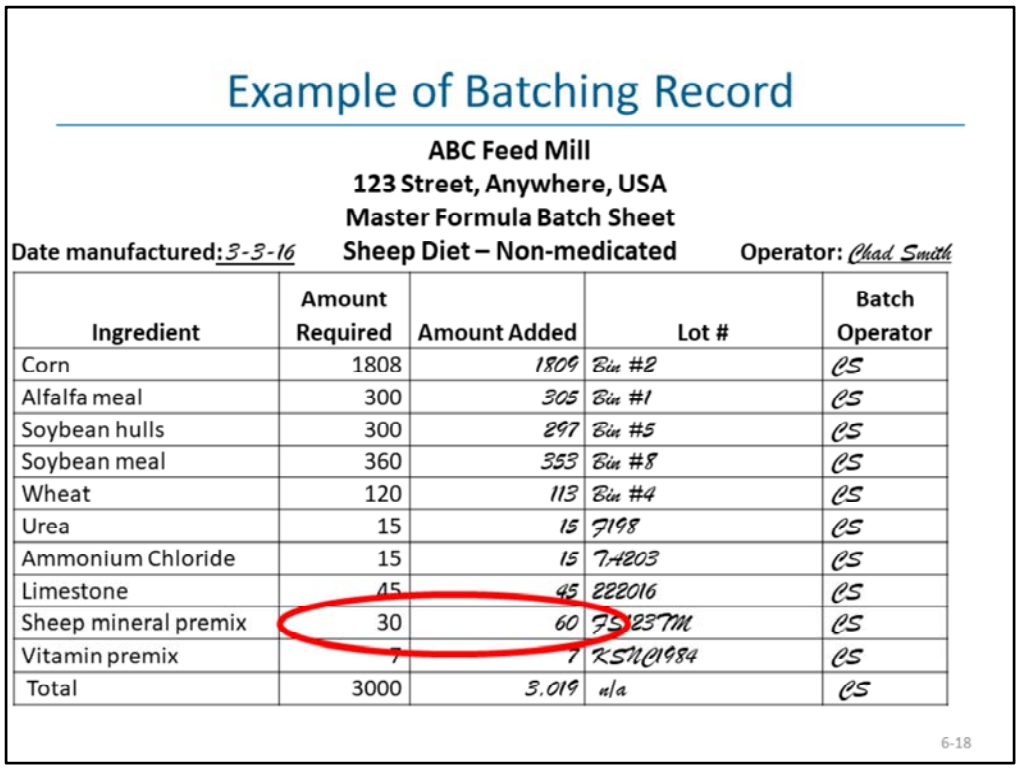
- A preventive control is not properly implemented and a corrective action has not been established, or
- A preventive control or the food safety plan is ineffective, or
- A Review of records finds that the records are not complete, activities did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.



(The requirement for corrective action procedures apply when a problem has been detected, regardless of whether the animal food has left the facility or not. If the animal food has entered commerce and there is a food safety concern because a failure of a preventive control has been identified, the facility must conduct a corrective action, as well as a recall. Required components of a recall plan are listed in 21 CFR 507.38 and described in Chapter 10: Recall Plan.)

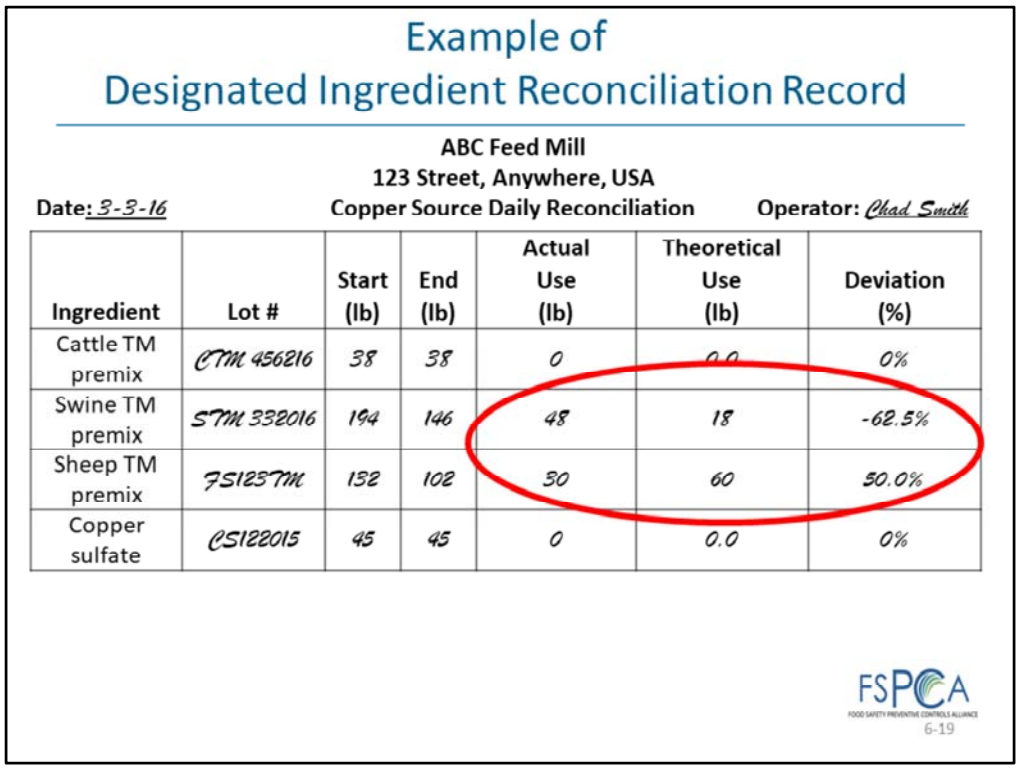
In the event of an unanticipated animal food safety problem as described in the previous slide, the facility must:

- Identify the problem
- Fix the problem by taking steps to correct what went wrong
- Take action to make sure that the problem does not continually happen
- For any animal food that was impacted, determine if the food is safe
- Prevent the impacted animal food from entering commerce if it is adulterated
- Reanalyze the food safety plan when necessary

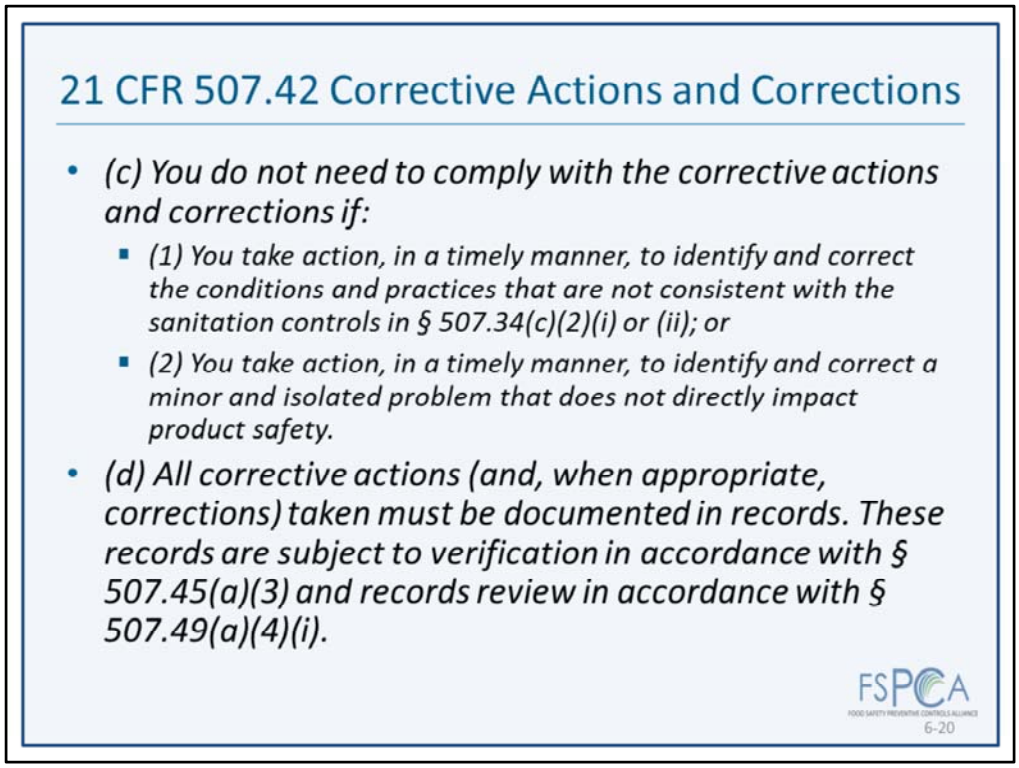


An example of when a corrective action may be required using the previous example of Preventive Control #2 is shown here. The batching operator observed there was a significant discrepancy in the “Amount Required” and the “Amount Added” for the sheep mineral premix added to the batch. In fact, it appears that ingredient was potentially inadvertently added twice. The batch operator identified the discrepancy since the facility requires monitoring through batch-to-batch reconciliation of ingredients. Because of the inclusion of double the sheep mineral pre-mix, a corrective action may be required to ensure the animal food is safe for sheep.

Corrective actions may include diverting the animal food to another species or blending the animal food until it has a safe level of copper for sheep. If this occurred, the facility should reanalyze the SOP and may need to retrain the qualified individual(s) to ensure that the batching operator knows and follows the SOP, including the addition of the appropriate ingredients at the right quantities to the animal foods.



Another example of when a corrective action may be required is shown here. During daily reconciliation of designated ingredients, the batching operator observed there was a greater than 10% deviation between theoretical and actual use in swine mineral premix and sheep mineral premix. This process reveals that potentially an employee unintentionally included swine mineral premix in place of sheep mineral premix. This would not have been caught by a batching record, because the correct quantity of premix was used, but the incorrect premix was included. Using the incorrect mineral premix may cause copper toxicity in sheep, so corrective action is necessary.

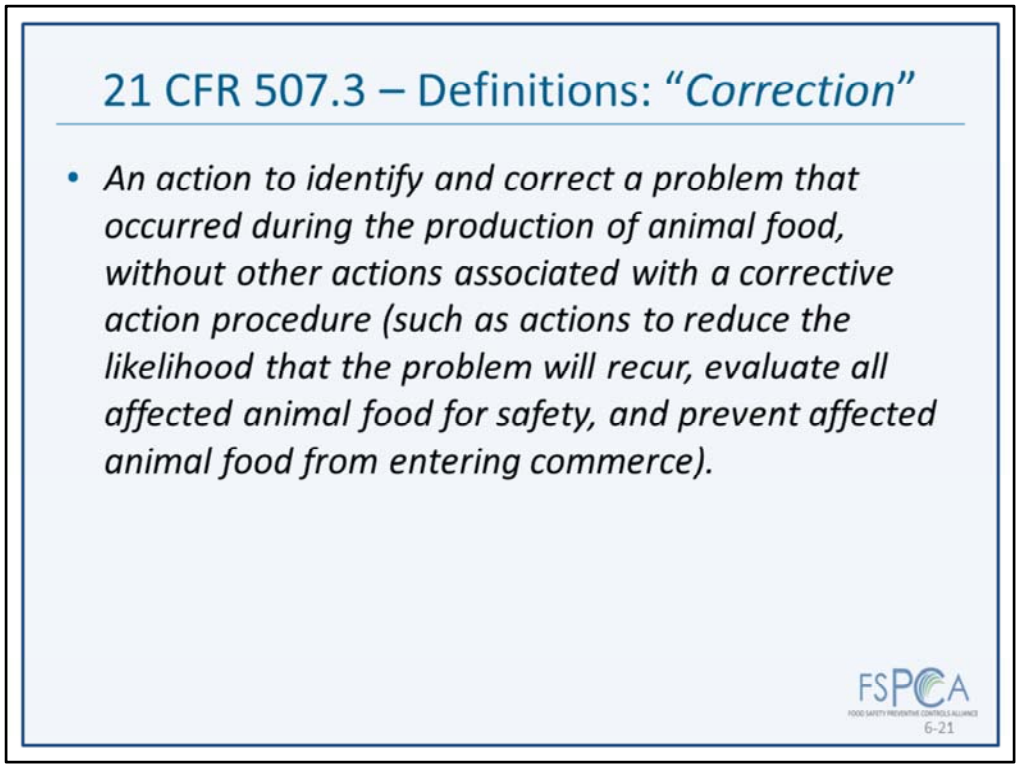


A facility does not need to comply with the all the requirements for a corrective action discussed previously if action is taken in a timely manner to:

- Identify and correct the conditions and practices that are not consistent with sanitation controls; or
- Identify and correct a minor and isolated problem that does not directly impact product safety.

The regulatory text in 21 CFR 507.42(c) applies to circumstances of when a correction would be appropriate compared to a corrective action. A definition of the term *correction* is on the next slide.

The last requirement for corrective actions (and when appropriate, corrections) is that they be documented. These records are subject to verification and records review.



The definition of correction is *"An action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce)."*

The difference between a correction and corrective action will be explained in greater detail in Chapter 8: Sanitation Preventive Controls. Think of a correction as something that can be done immediately to correct a problem to reduce the chance that an animal food with a food safety problem will enter commerce.

Exercise 6

- In the same small groups as Exercise 5:
  1. Choose one *hazard requiring a preventive control*. If you did not have one, select one for the purpose of this exercise.
  2. Complete the blank Table 2 from Exercise 6 in the Exercise Workbook for that ingredient and process step.
  3. Discuss among your groups:
     a. Are there parameters for this hazard? If so, what are they?
     b. Is monitoring a required component? If so, what, how, when, and who will conduct the monitoring?
     c. What are appropriate corrective actions or corrections for the preventive control?
     d. What records will be generated to document the monitoring and corrective actions for preventive control management?

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Exercise 6 Summary

- There are specific regulatory requirements that must be completed when managing preventive controls. However, there is flexibility in how to apply preventive control management components.
- Facilities may choose different methods with varying frequency when monitoring, and may have different approaches in corrections or corrective actions activities.
- Many records are required to document the preventive control management components to demonstrate the food safety plan is working as intended.

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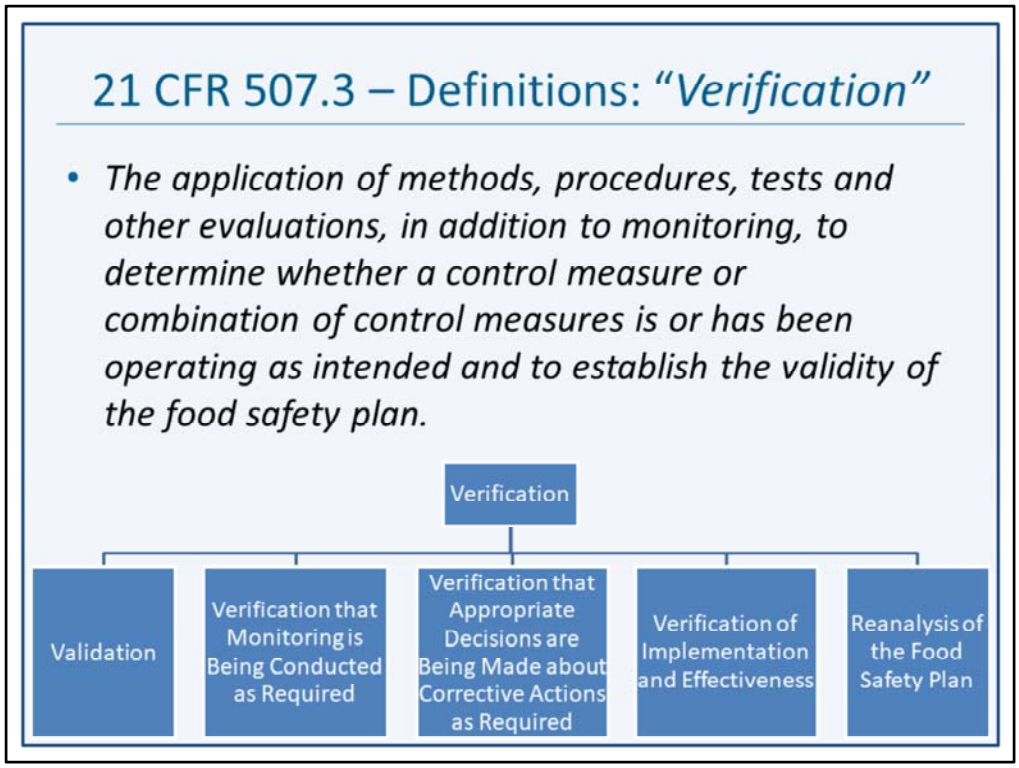
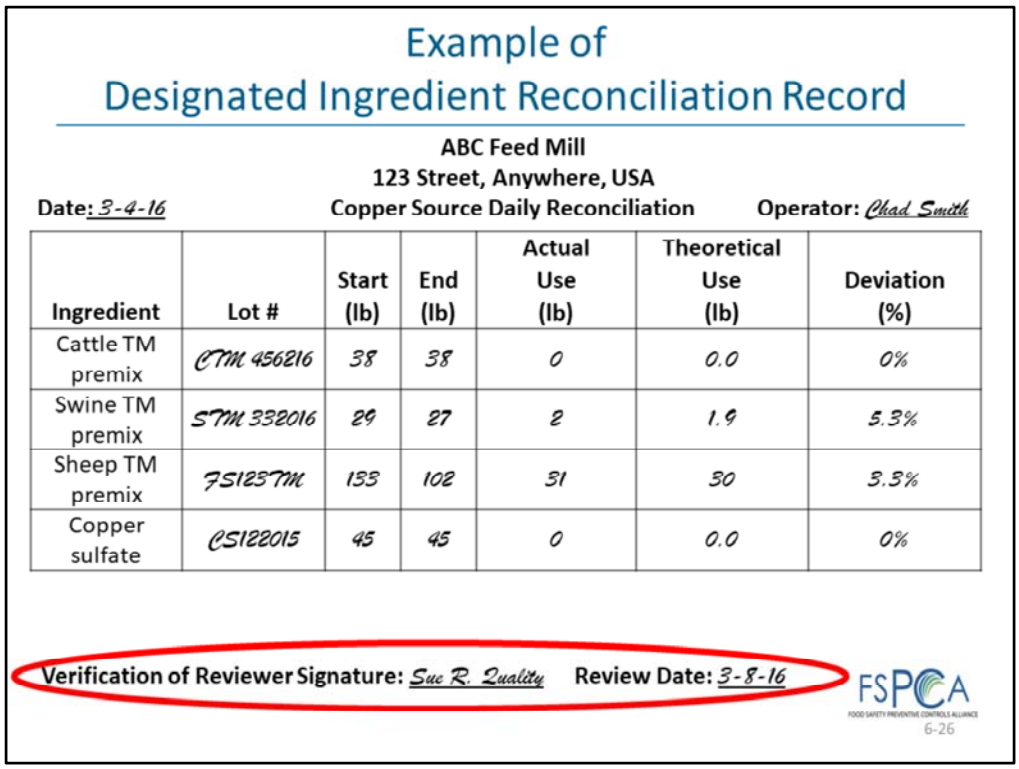


The next preventive control management component is verification. The definition of verification is "*the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan*."

The requirements of verification are found in 21 CFR 507.45, which are found on page 56347 of the *Preventive Controls for Animal Food* rule in Appendix 1. This section cross-references with other preventive control management components.

There is flexibility in how a facility conducts verification activities. Where appropriate, verification activities must include:

- Validation of the preventive control
- Verification that monitoring is being conducted
- Verification that the appropriate decisions about corrective actions are being made
- Verification of implementation and effectiveness
- Reanalysis of the food safety plan, which was described in Chapter 4.



Example of Designated Ingredient Reconciliation Record

ABC Feed Mill
123 Street, Anywhere, USA

Date: 3-4-16 **Copper Source Daily Reconciliation** **Operator:** Chad Smith

Ingredient	Lot #	Start (lb)	End (lb)	Actual Use (lb)	Theoretical Use (lb)	Deviation (%)
Cattle TM premix	CTM 456216	38	38	0	0.0	0%
Swine TM premix	STM 332016	29	27	2	1.9	5.3%
Sheep TM premix	FS125TM	133	102	31	30	3.3%
Copper sulfate	CS122015	45	45	0	0.0	0%

Verification of Reviewer Signature: Sue R. Quality **Review Date:** 3-8-16

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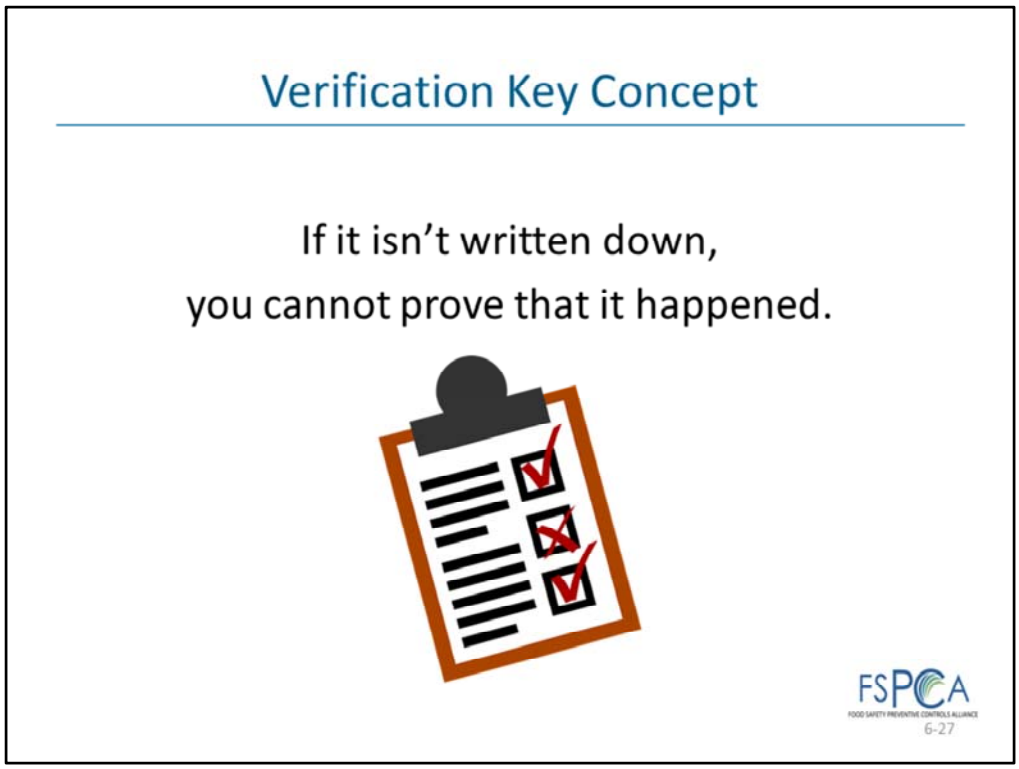
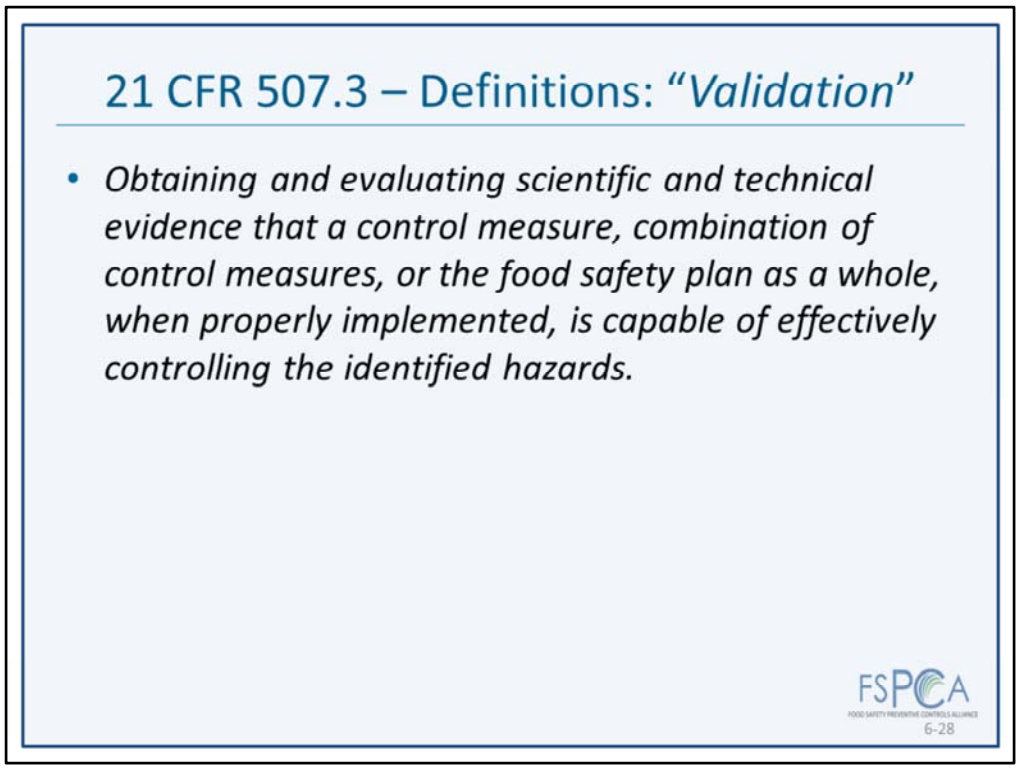
(The PCQI is responsible for reviewing records, but may designate an individual to conduct this activity as long as the individual providing the verification is properly trained and the verification is still overseen by the PCQI such as through periodic spot checks of the records.)

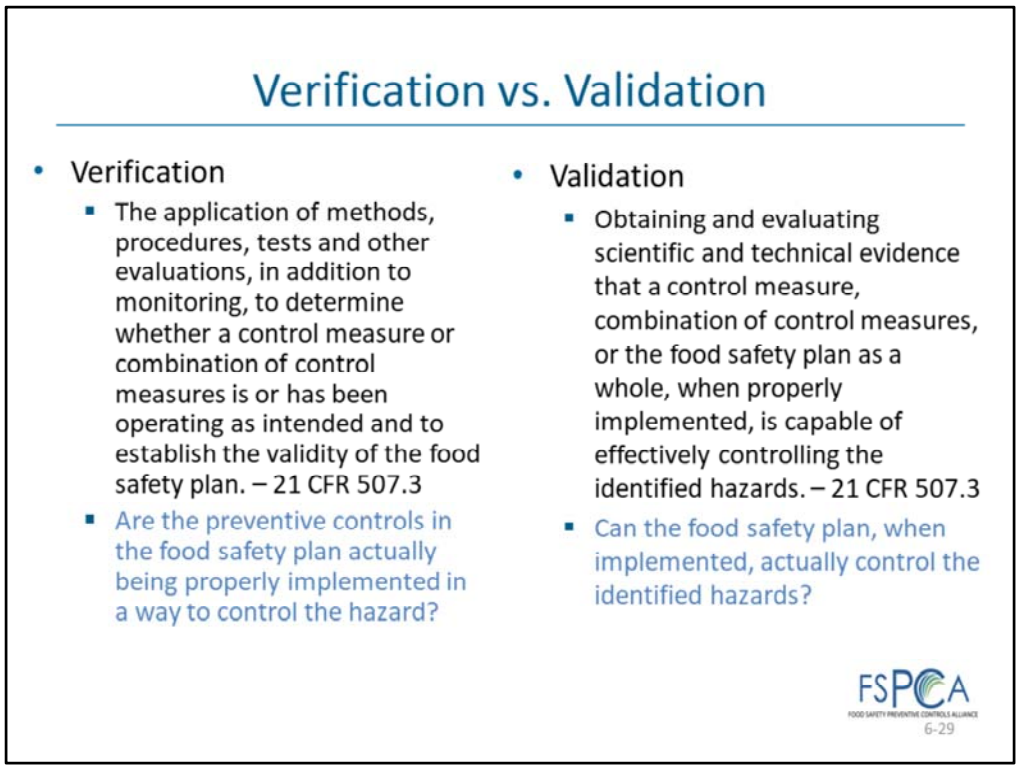
Using the previous example of Preventive Control #2 (weighing all ingredients and recording the weight) in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds, the verification activities require weekly review of the daily reconciliation sheet by the PCQI. As described previously, daily reconciliation of designated ingredients was a monitoring step for the preventive control. Verification to ensure the preventive control is working is the review of the monitoring record by the PCQI at the end of each week. The PCQI is required to review the records within 7 working days according to the regulation and according to the facility's SOP for daily recognition of designated ingredients. Therefore, if the PCQI is not available then the PCQI must designate an individual to verify the records or create written justification as to why the records will not be reviewed within 7 working days. Even then, the PCQI is responsible for the oversight of the records and verification process.



Verification is used to ensure that preventive controls are working as the facility intended. To verify, a facility will need to document. If the activity is not written down, a facility cannot prove that it happened. Written documentation of verification activities and justification are required.

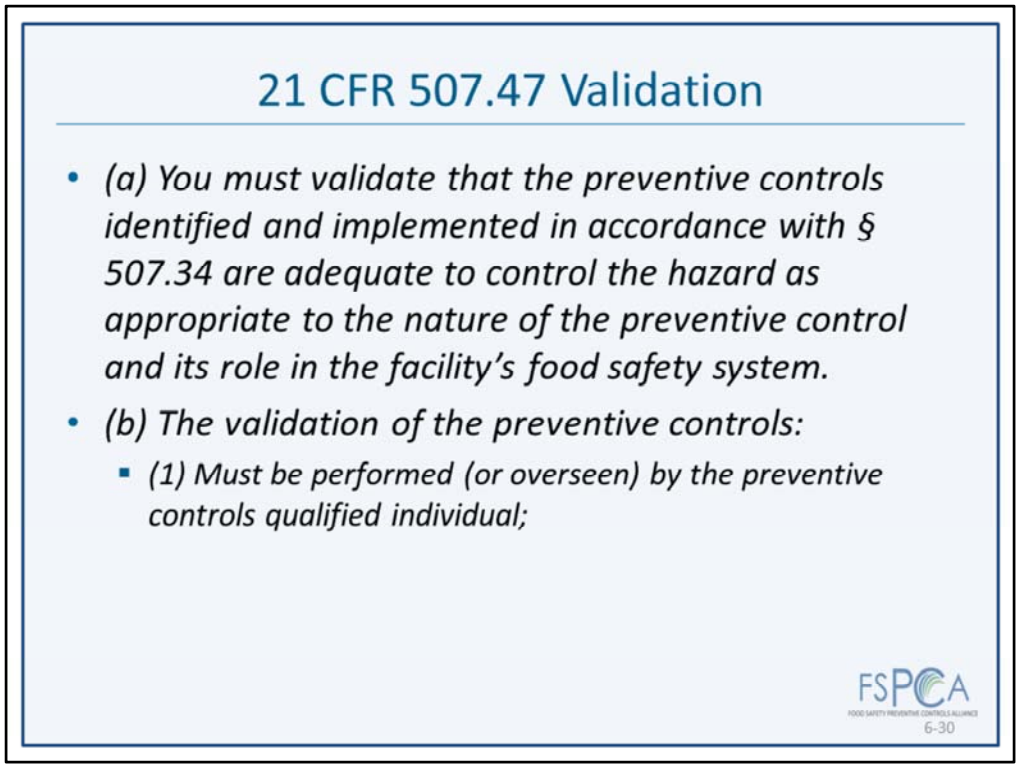


The concept of validation is part of verification. This is a defined term in the *Preventive Controls for Animal Food* rule. Validation is *"obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."*

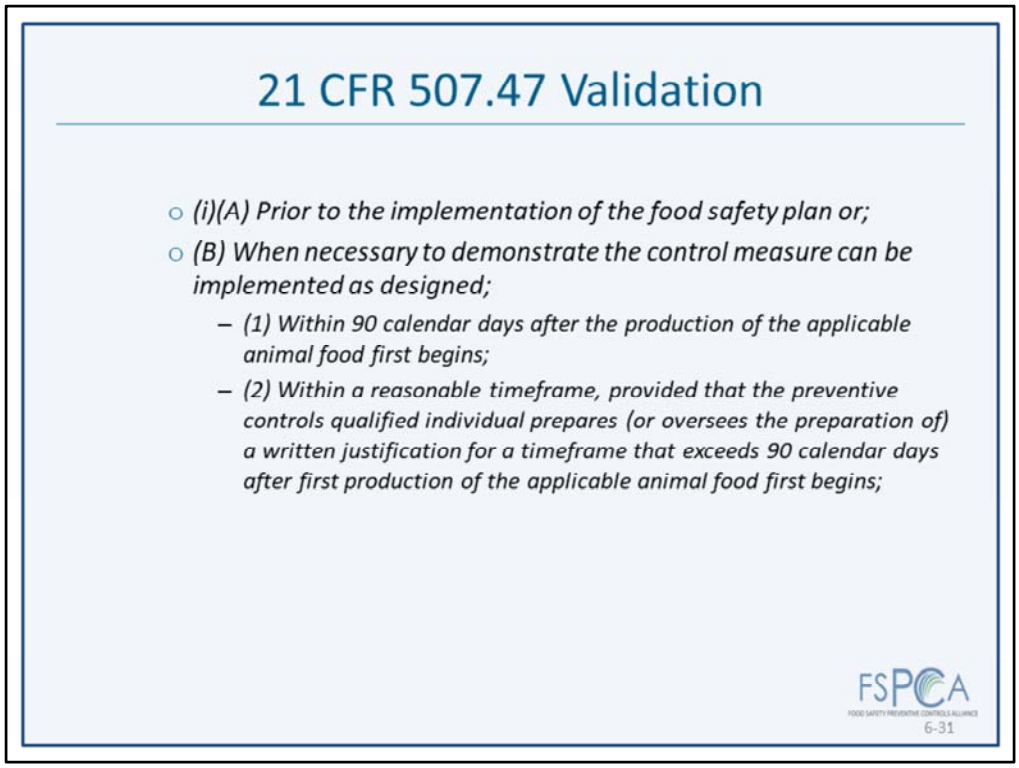


Both verification and validation are essential for an effective animal food safety system. Because they sound similar, they are easy to confuse. This slide summarizes their differences. Routine *verification* is an ongoing process to provide evidence that the food safety plan is being properly implemented and operating as intended. In general, it helps the facility answer the question: Are the preventive controls in the food safety plan actually being properly implemented in a way to control the hazard?

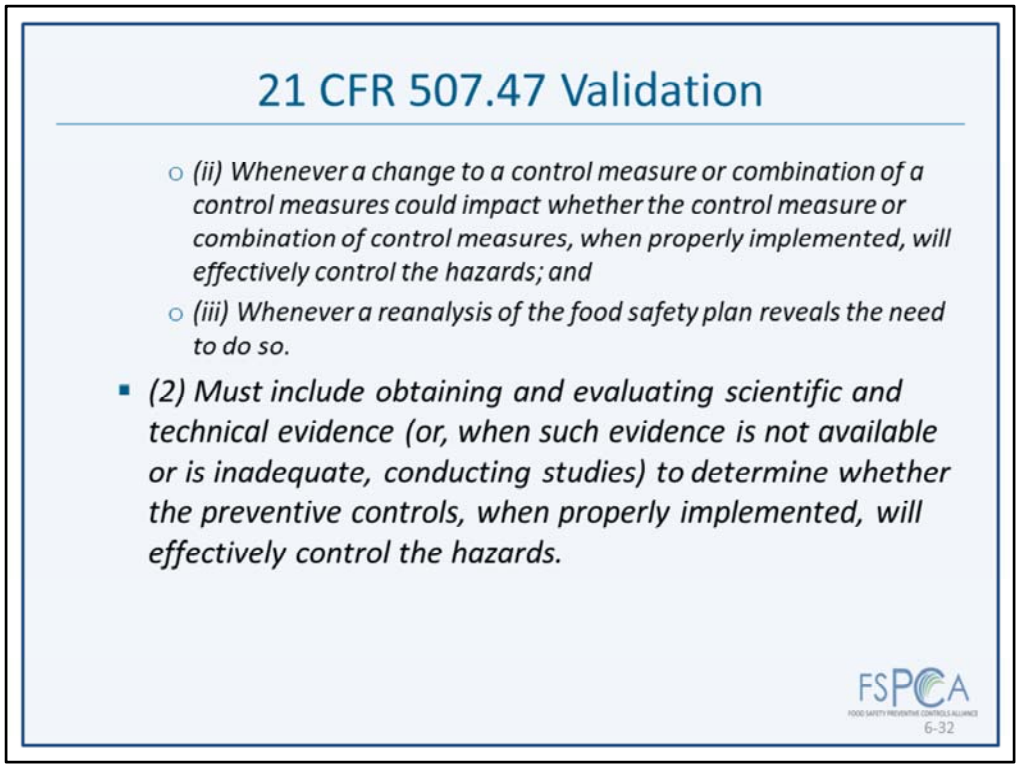
Meanwhile, *validation* is the demonstration that following the food safety plan will actually control the identified hazards. This concept helps the facility answer the question: Can the food safety plan, when implemented, actually control the identified hazards? Thus, validation should be conducted prior to implementation of the food safety plan, when appropriate.



The facility must validate that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and it role in the facility's food safety system. The validation of the preventive control must be performed by the PCQI.



Validation must be performed (or overseen) by a PCQI. There are several situations when validation is required. Prior to the implementation of the food safety plan or when necessary to show a preventive control can be implemented, the facility must validate the preventive control within 90 calendar days after the production of animal food first begins. If additional time is needed and the validation does not occur in the first 90 days, the PCQI must provide written justification for validation to occur in a reasonable timeframe.

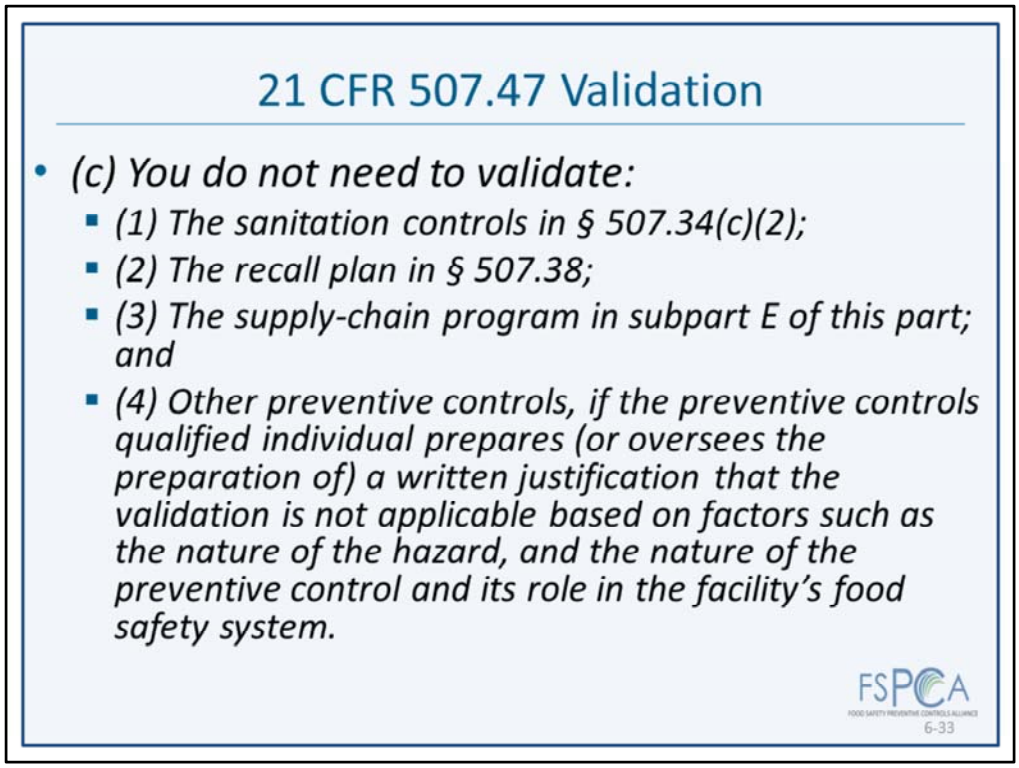


The next time validation is required is whenever there is a change to a preventive control that could impact the effectiveness of the control. Validation is also required whenever the reanalysis of the food safety plan identifies the need for additional validation.

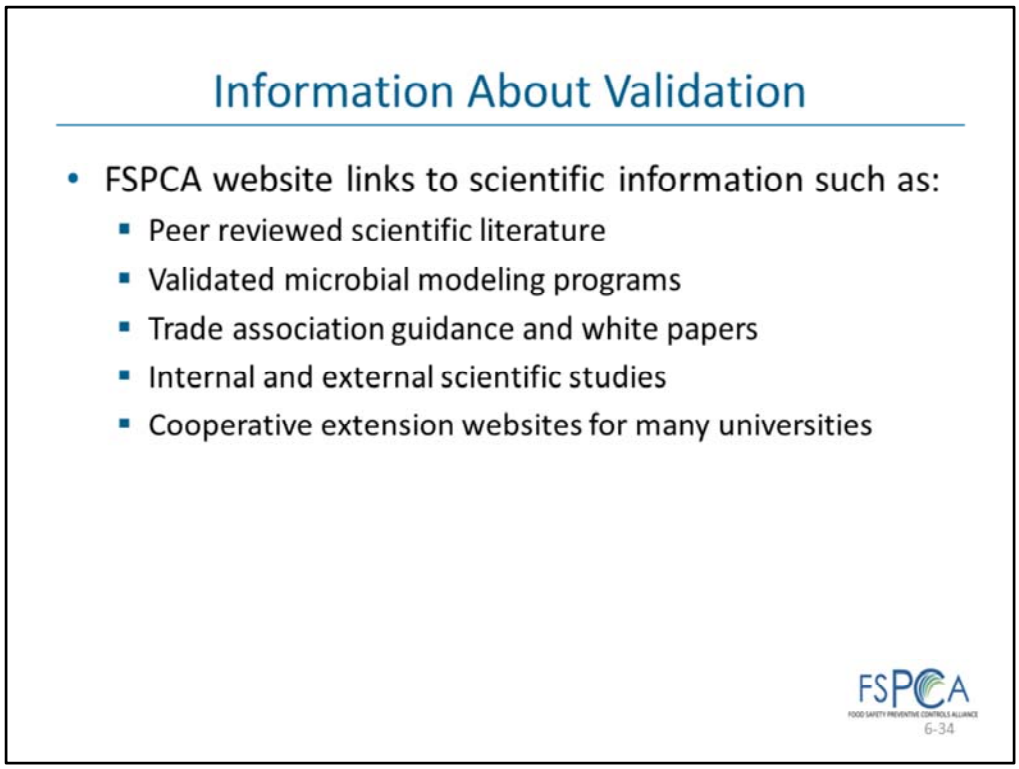
When validation is needed to show that a preventive control can be properly implemented, validation must include obtaining and evaluating scientific and technical evidence to determine whether the preventive control will effectively control the hazard. This technical evidence may be from scientific and technical reports. There may be situations in which that evidence does not exist. To get the necessary data, a facility may conduct in-house studies.

An example of using existing scientific and technical data can be seen in the pet food industry in the control of *Salmonella*. Scientific data demonstrates that pet food processed at 178°F (81°C) with moist heat (22% moisture) is adequate for instantaneous *Salmonella* destruction of 10^6 log initial population. If this scientific data is referenced, it should be properly cited and understood by the PCQI. It is not mandatory to include in the food safety plan, but may be helpful for communication purposes.

In the livestock food industry, there may be a lack of scientific or technical data for the control of hazards. Furthermore, there are a wide variety of factors that change from one facility to another, such as ingredients, equipment, and process design. In this case, facilities manufacturing animal food for these species may need to rely on in-house studies and testing of processes to validate the effectiveness of a preventive control.



There are certain preventive controls that do not need to be validated. A facility does not need to validate sanitation controls, the recall plan, or the supply-chain program. Other preventive controls, do not need validation if the PCQI prepares a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

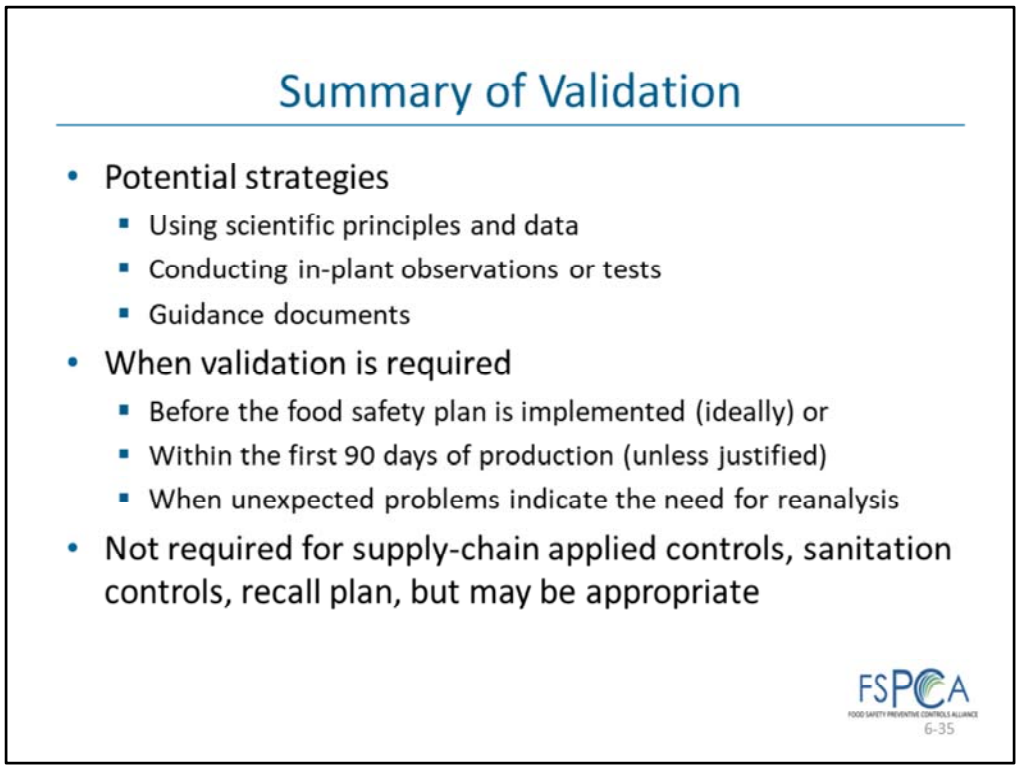


(Additional links to relevant information will be added to the FSPCA website as they become available. As described in previous chapters, the appropriate control measures and parameters are specific to the type of animal food and its manufacturing environment. However, there is not available scientific and technical data for every situation. For example, there is limited data to describe necessary time × temperature combinations to destroy *Listeria monocytogenes* in pet food. In this case, scientific literature in human food may be appropriate.)

Because scientific and technical data is required for validation, the Food Safety Preventive Controls Alliance has gathered links to information that may be relevant for animal food manufacturing facilities. Links to this data is available on the Alliance's website, such as peer reviewed scientific literature, validated microbial modeling programs, trade association guidance and white papers, examples of internal and external scientific studies, and links to the cooperative extension service websites for many land-grant universities.

Note that Preventive Control # 2 (weighing all ingredients and recording the weight) used in the copper toxicity example is an example of a preventive control that does not have validation. The justification for not having validation is that the preventive control – procedures for ensuring correct manual weighing and addition of sheep mineral premix – does not have a possible validation because one cannot validate accurate hand addition with scientific or technical data. The facility may be able to reference scientific literature that establishes maximum levels of copper for sheep food in their food safety plan, but the actual hand addition is not something that can be validated. Some preventive controls will

not have validation because they cannot be validated. This is acceptable because the rule states, “/as appropriate to the nature of the preventive control and its role in the facility’s food safety system.” The other two preventive controls for copper toxicity (PC #1 and PC #3) in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds are examples of preventive controls that can be validated.



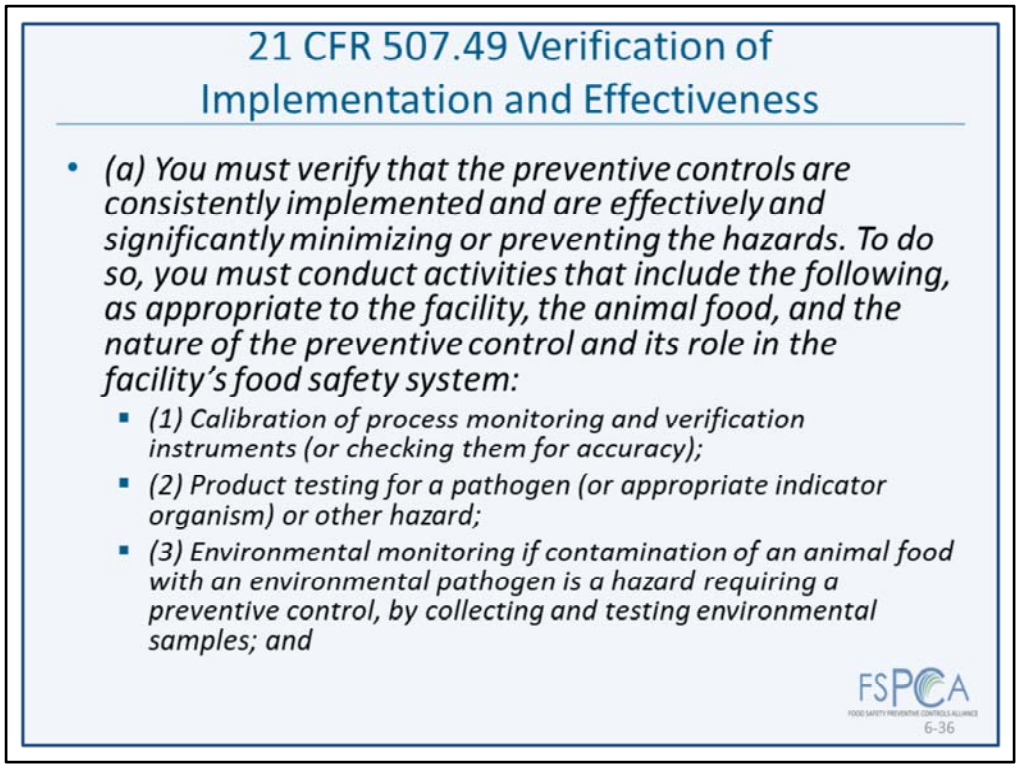
In summary, the purpose of validation is to provide objective evidence that *process* preventive controls have a scientific basis and represent a "valid" approach to controlling the hazards associated with a specific product and process. This includes demonstrating that the equipment can deliver the process as designed and that the design parameters actually will control the hazard requiring a preventive control. Strategies that can be used to validate the food safety plan include:

- using scientific principles and data from the literature
- relying on expert opinion
- conducting in-plant observations or tests at the limits of its operating controls
- using mathematical models
- incorporating regulatory guidelines

Because of the scientific concepts involved in validation, this element of preventive controls must be performed or overseen by a *Preventive Controls Qualified Individual*.

Validation must be done before implementing a preventive control identified in the food safety plan, when first making a new animal food, there is a change to the manufacturing process, or there is a problem that causes an evaluation to see if the preventive control is effective.

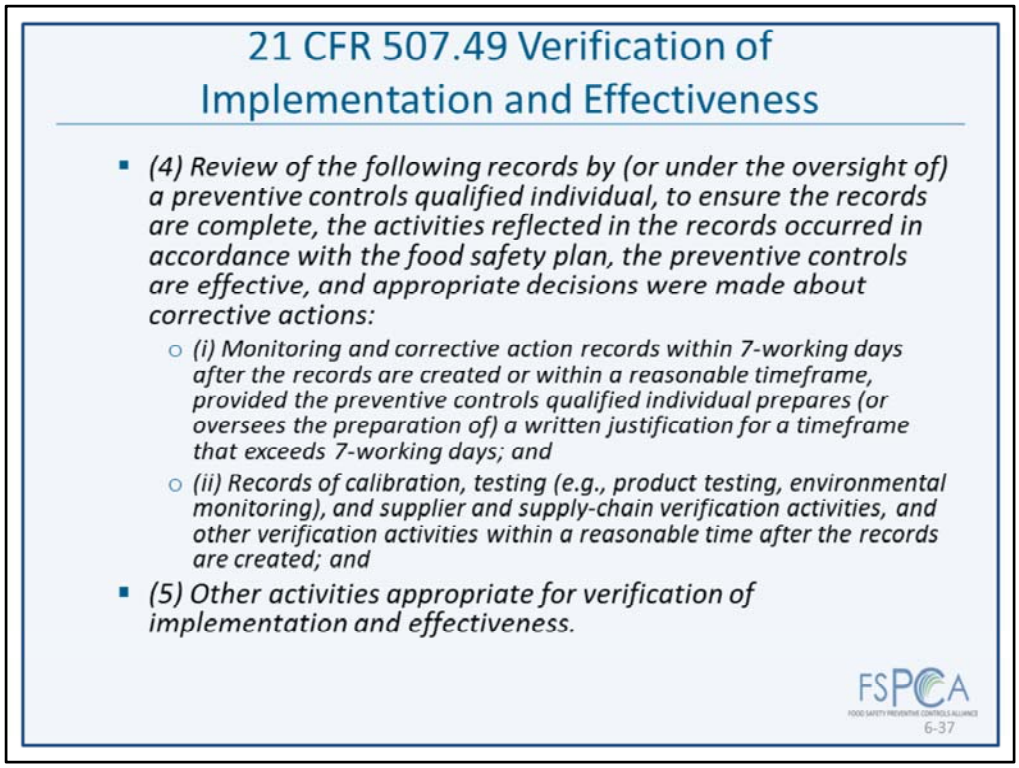
Validation is not required for supply-chain-applied controls, sanitation controls, or other preventive controls (if justified by the PCQI). A facility is also not required to validate the recall plan.



(While 7 days is the listed requirement, there are acceptable exceptions for a longer review time. An extension beyond 7 working days requires justification and supporting documentation.)

In addition to validation, another component of the required verification of preventive controls is verification of their implementation and effectiveness. This is a required management component of all preventive controls. The concept is that the facility must verify that the preventive control(s) identified in the food safety plan are being consistently applied and that they significantly minimize or prevent the hazard.

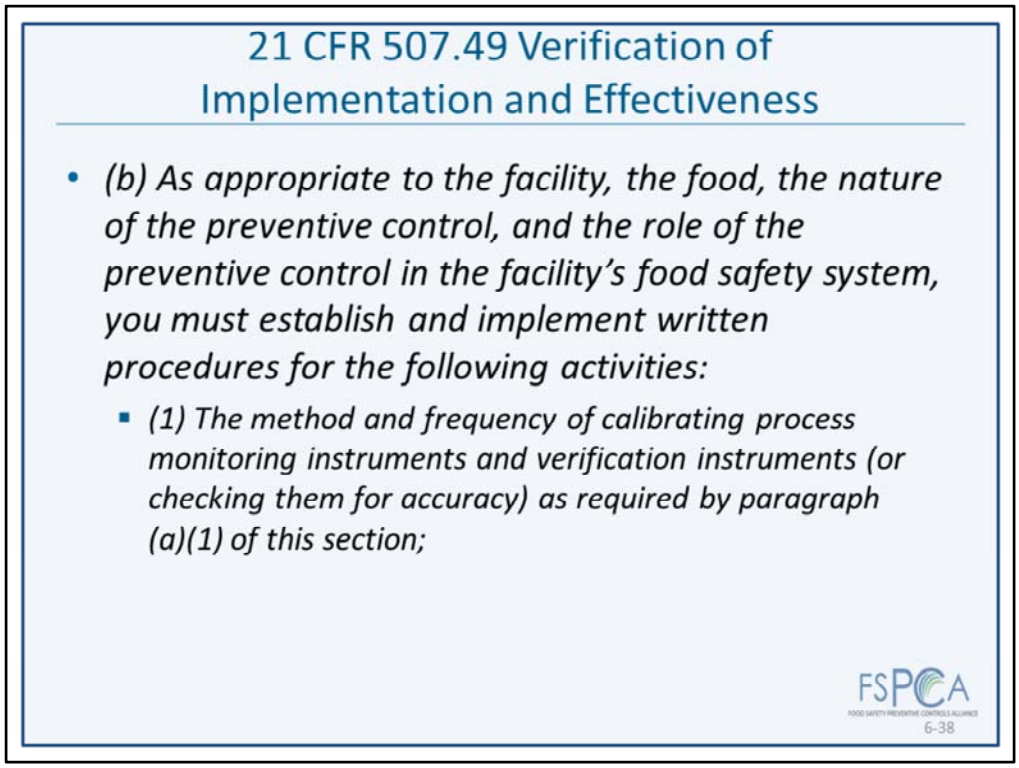
Examples of verification of implementation and effectiveness activities include:
- Calibration of instruments (such as thermometers and scales) to ensure their accuracy
- Product testing (such as for pathogens or nutrient deficiencies or toxicities);
- Environmental monitoring (such as for *Salmonella* spp. or *Listeria monocytogenes*)



Additional examples of verification of implementation and effectiveness activities include:

- PCQI reviewing records, such as those for monitoring and correction actions, within 7-working days after they were created, or a reasonable timeframe if justified by the PCQI; and
- Other activities deemed appropriate by the PCQI

Several types of verification activities may be necessary for each preventive control to ensure that the procedures used are effective. However, not all of the examples of verification of implementation and effectiveness activities are appropriate for all hazards. For example, environmental monitoring is usually not appropriate if a facility does not have a biological hazard that requires a preventive control. The activities that are conducted for verification of implementation and effectiveness should be appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system.

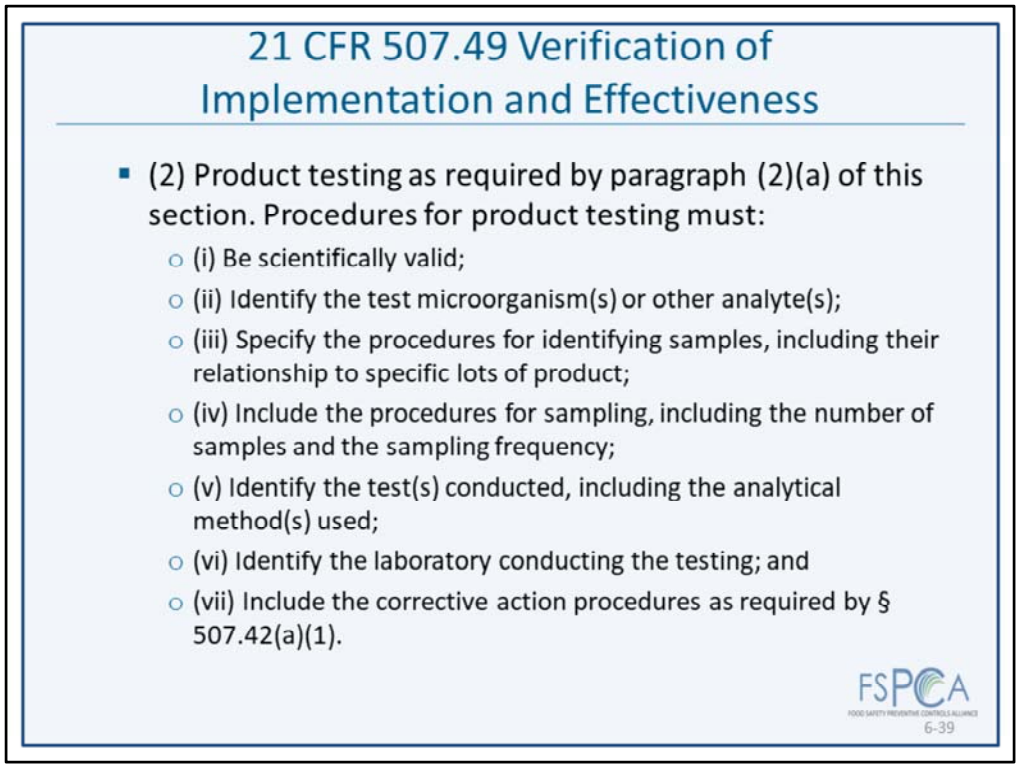


The facility must establish and implement written procedures, such as standard operating procedures, for:

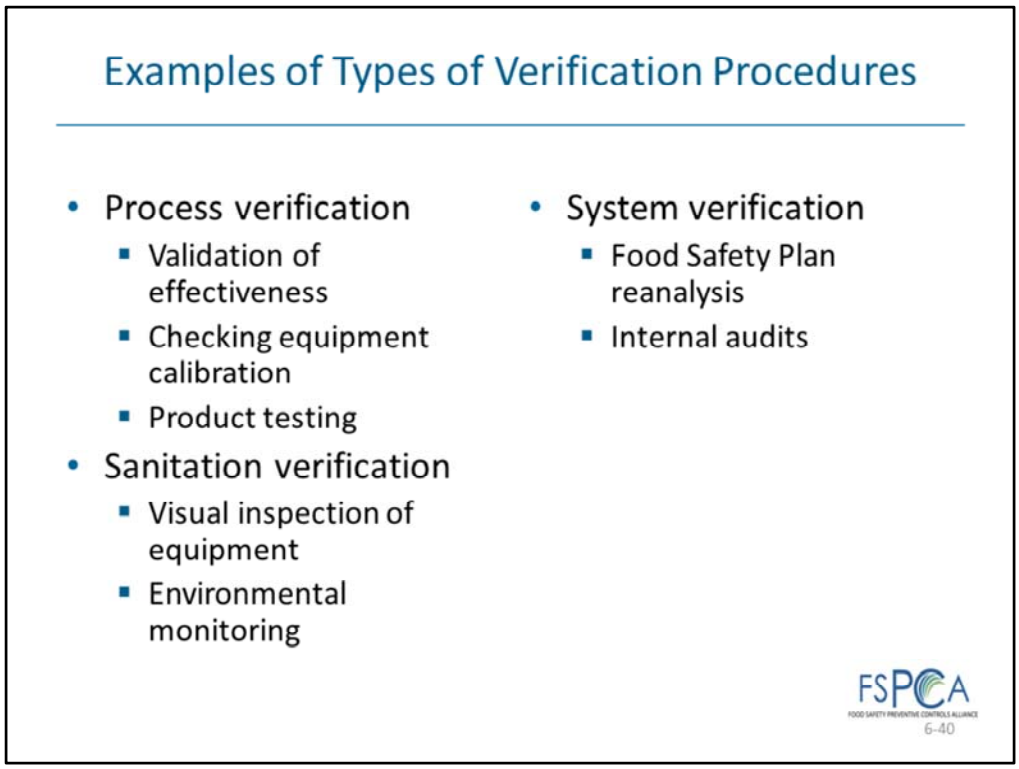
- Method and frequency of calibrating instruments
- Environmental monitoring
- Product testing

In animal food manufacturing facilities, the type of instruments that require calibration may vary. For example, pet food facilities utilizing extrusion as a kill step for biological hazards would calibrate thermometers and temperature gauges. Alternatively, other animal food manufacturing facilities would calibrate scales by semi-annual scale certification. Written procedures for these activities may already exist in the facility prior to their implementation in the food safety plan. Oftentimes, the standard operating procedures used to conduct those activities are adequate for this management component.

The requirements for environmental monitoring are not covered in this chapter but are discussed in Chapter 8: Sanitation Preventive Controls. Requirements for product testing are described next.

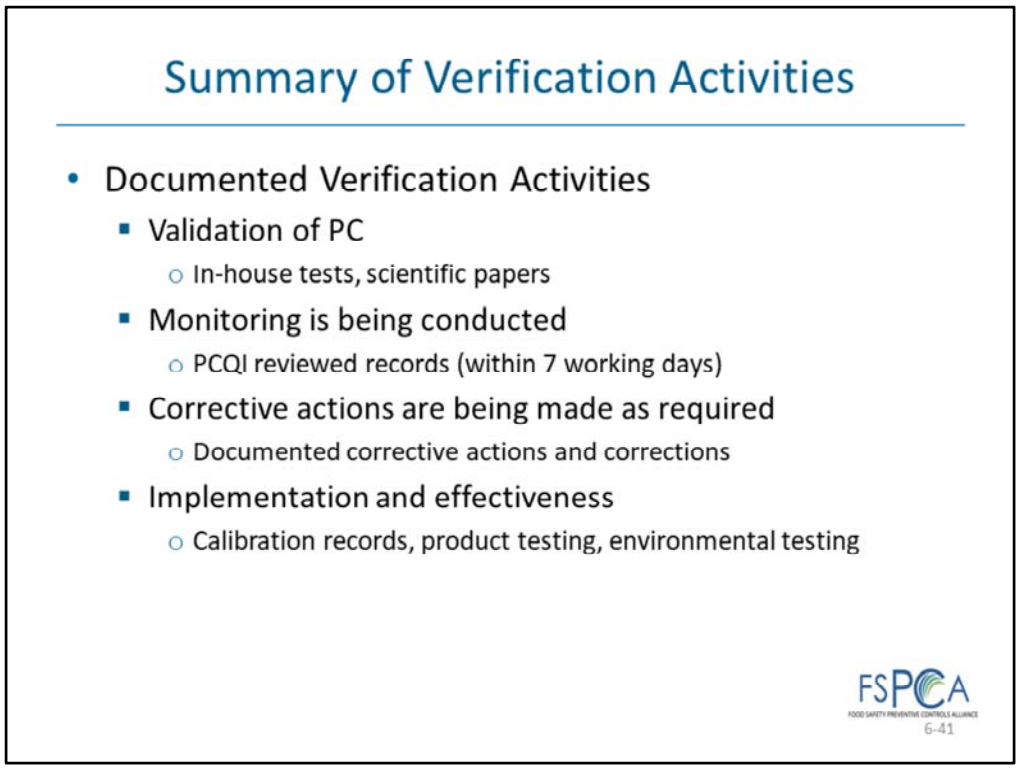


To verify that a hazard is being significantly minimized or prevented by a preventive control, product testing may be appropriate. The use of product testing is usually most appropriate for biological hazards, but it may also be used to verify the implementation and effectiveness of other preventive controls, such as a preventive control to prevent a nutrient deficiency or toxicity. Product testing may be accomplished through a number of methods, including in-line or finished product analysis.

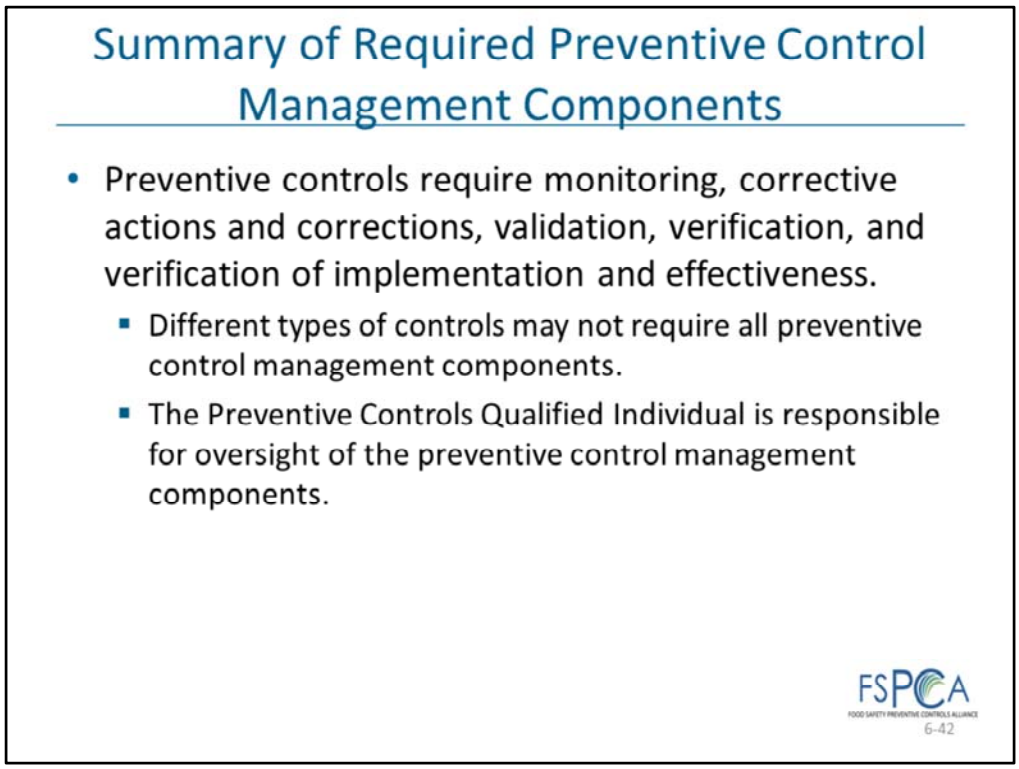


Validation is one type of verification activity. Validation (i.e., making sure that the process actually controls the hazard) is required for most process controls. Validation, when required, is preferably done before the plan is implemented.

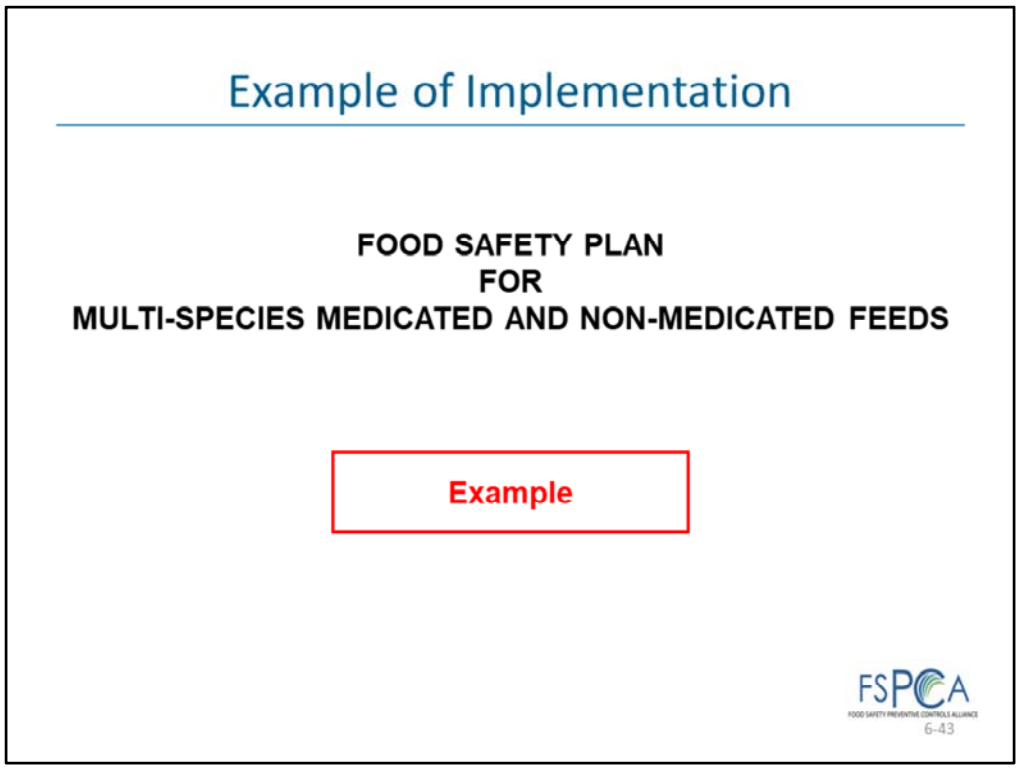
Other elements of verification are typically ongoing procedures that may be regularly scheduled, such as calibration of equipment (e.g., the temperature monitoring device for the extruder) or record review (e.g., documenting the correct manufacturing sequence was used when manufacturing animal food intended for sheep). Some verification activities are done less frequently, such as in-process or end product testing or internal audits. As with validation, required verification activities vary depending on the facility and other factors. Regulatory inspections are yet another type of verification activity in which the inspector reviews the adequacy of the food safety plan, determines if it is being properly implemented, and reviews records to see if parameters are continually met and corrective actions are adequate.



In summary, there are many components of verification, and those components must be documented. These requirements include validation of the preventive control, as appropriate, verification that monitoring and corrective actions are being conducted as necessary, and records of preventive control implementation and effectiveness, such as calibration records, product testing, and environmental monitoring.



To close, preventive controls have required management components to ensure they significantly minimize or prevent hazards. These management components include monitoring, corrective actions and corrections, validation, verification, and verification of implementation and effectiveness. The PCQI is responsible for the oversight of these components.



As with Chapter 5, the next section describes one example of how a facility may choose to organize and document the preventive controls management components. We will continue to use Preventive Control #2 from the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Livestock Feeds as the hazard example. This is Table 2 and 3 in the example plan. This is also the format that will be used to describe the application of process preventive controls, sanitation preventive controls, and supply-chain-applied controls in Chapters 7, 8, and 9, respectively.

As with Table 1, color is used to denote different parts of Table 2. Green (columns 1 through 5) indicates the part of the table describing the preventive control, while purple (columns 6 through 8, Table 3) indicates columns that are specific management components for those controls.

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	Procedures for ensuring correct manual weighing and addition of sheep mineral premix	2	Process Control	10% deviation between theoretical and actual use

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The first set of columns in Table 2 is a summary of information determined in Table 1. These include the *hazard requiring a preventive control*, its appropriate preventive control, its preventive control number, and the type of preventive control. The procedures for ensuring correct manual weighing and addition of sheep mineral premix is preventive control #2, which is a process control. The next column provides an area to document parameters for the preventive control. Not all preventive controls will have parameters, but this preventive control includes the acceptable tolerance of a 10% deviation between the actual and theoretical use of designated ingredients.

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	Use of designated ingredients in each batch and throughout day	Reconciliation of designated ingredients: 1) Batching records; and 2) Daily actual vs. theoretical total use	Daily	Batching operator

6-45

In order to help participants follow along, Column 1 is shown again in this slide and the next slide. However, the description of the management components follows with Column 6, monitoring, which is separated into four different sub-columns.
The monitoring of the preventive control is to monitor the use of designated ingredients (added copper ingredients and sheep mineral premix) in each batch and over a single day. This will be accomplished through reconciliation of designated ingredients in batching records and total daily theoretical vs. actual differences for the designated ingredients. Reconciliation will occur for each batch and at the end of each day, and the monitoring activity is the responsibility of the batching operator.

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	Batching records, daily designated ingredient reconciliation records, corrective action records

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If monitoring reveals that the process control has failed – or in this case, the deviation between the theoretical and actual use of designated ingredients is greater than 10%, in theoretical use, a corrective action is necessary. This facility's corrective action is one of the following:

- Diverting the animal food to another species; or
- Blending the animal food until it has a safe level of copper for sheep; or
- Holding and testing affected product to ensure safe copper concentration; or
- Safely disposing of animal food

In order to conduct these activities effectively, applicable documentation records include the batching records, designated ingredient reconciliation records, and corrective action records.

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
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	Daily scale accuracy checks Annual scale calibration
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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The final management component is verification. The monitoring and corrective action records will be reviewed within 7 working days by the PCQI or their designee of the documented action unless otherwise justified. There is no validation for this preventive control.

Finally, reanalysis of the plan is conducted every 3 years or as otherwise necessary. The Example Animal Food Safety Plan for Multi-Species Medicated and Non-Medicated Livestock Feed ends with a recall plan. A discussion of this plan is in Chapter 10: Recall Plan.

Now that participants have a clearer view of the hazard analysis and preventive controls determination, as well as the required management components for those preventive controls, the next few chapters will focus on the application of examples through different preventive controls.