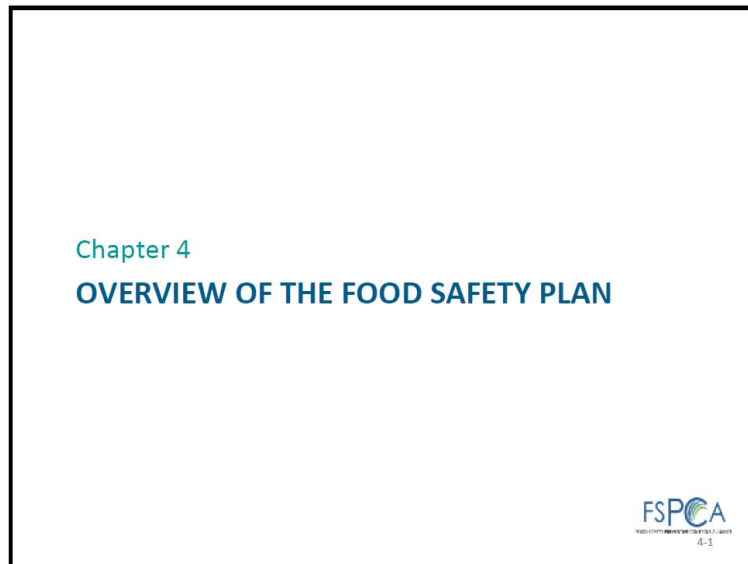



CHAPTER 4. Overview of the Food Safety Plan



Slide 1

While Current Good Manufacturing Practices are a key component of ensuring a successful food safety system, the majority of this curriculum focuses on Subpart C of the *Preventive Controls for Animal Food* rule, which are the requirements for Hazard Analysis and Risk-Based Preventive Controls. The first requirement in subpart C is the requirement for a food safety plan. This chapter will introduce the requirements associated with that plan.

Food Safety Plan Overview Objectives



In this module you will learn:

- The required elements of a written food safety plan.
- The principles applied to build a food safety plan.
- When the food safety plan must be reanalyzed.

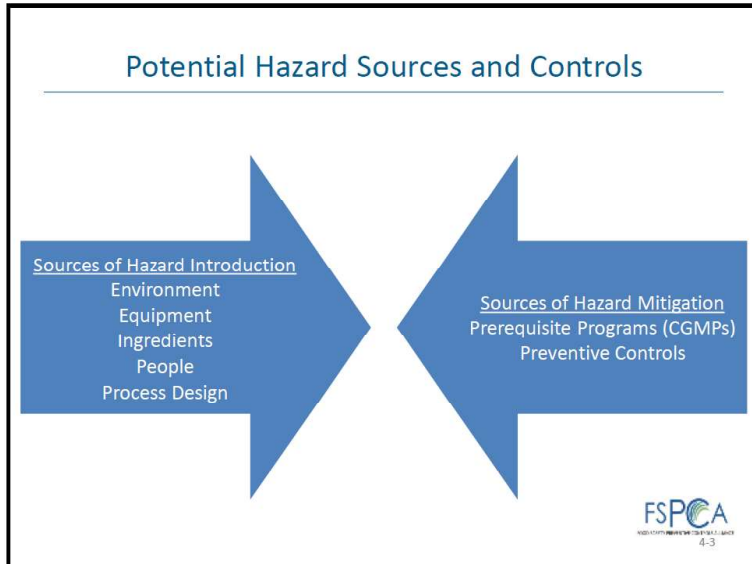
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Slide 2

In this chapter, the required elements of a food safety plan will be discussed, as well as the principles that must be applied to build the plan successfully.

The specific format of a food safety plan is not defined by the regulation. Each facility can organize the required information in a manner that suits their systems, the needs of their employees, the needs of their customers, and the requirements of the regulation. The important thing is to have a plan that is easy to understand, implement and manage; that it is kept up to date; and that it is organized and accessible for inspection. The following is an example of how a food safety plan might be set up, using a notebook. There is also no requirement that all components of a food safety plan be contained in a single notebook – we are just using the picture as a model concept for development.

After the required elements of the food safety plan are discussed, this chapter will describe when the food safety plan must be reanalyzed.

**Slide 3**

Chapter 3 described the biological, chemical, and physical hazards typically associated with animal food. These hazards can come from a variety of sources, such as the environment (cross-contamination of pathogens on dust in the air), equipment (cross-contamination of pathogens on surfaces), ingredients (mycotoxins), people (human error), or process design (drug carryover). A facility's food safety system utilizes prerequisite programs, such as CGMPs, and preventive controls to prevent or significantly minimize hazards so they are no longer an issue in animal food.

21 CFR 507.31 Food Safety Plan

- (a) *You must prepare, or have prepared, and implement a written food safety plan.*
- (b) *One or more Preventive Controls Qualified Individuals must prepare, or oversee the preparation of, the food safety plan.*



Note that when the *Preventive Controls for Animal Food* rule refers to 'you,' as it does in this section, the 'you' is the owner, operator, or agent in charge of the facility.

The owner, operator, or agent in charge of the facility is responsible for the hazard analysis described in this section. However, the owner, operator, or agent in charge of the facility may designate the responsibility of conducting the hazard analysis to the *Preventive Controls Qualified Individual*, as long as they recognize that the ultimate responsibility rests with the owner, operator, or agent in

Slide 4

The *Preventive Controls for Animal Food* rule requires that a facility implement a written food safety plan. This plan may be written by the facility, or written for it by someone else. The *Preventive Controls Qualified Individual* (PCQI) for the facility is responsible for its preparation, either directly or in an oversight capacity.

21 CFR 507.31 Food Safety Plan

- (c) *The written food safety plan must include:*
 - (1) *The written hazard analysis as required by § 507.33(a)(2);*
 - (2) *The written preventive controls as required by § 507.34(b);*
 - (3) *The written supply-chain program as required by subpart E of this part;*
 - (4) *The written recall plan as required by § 507.38(a)(1);*
 - (5) *The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);*
 - (6) *The written corrective action procedures as required by § 507.42(a)(1); and*
 - (7) *The written verification procedures as required by § 507.49(b).*
- (d) *The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.*



Slide 5

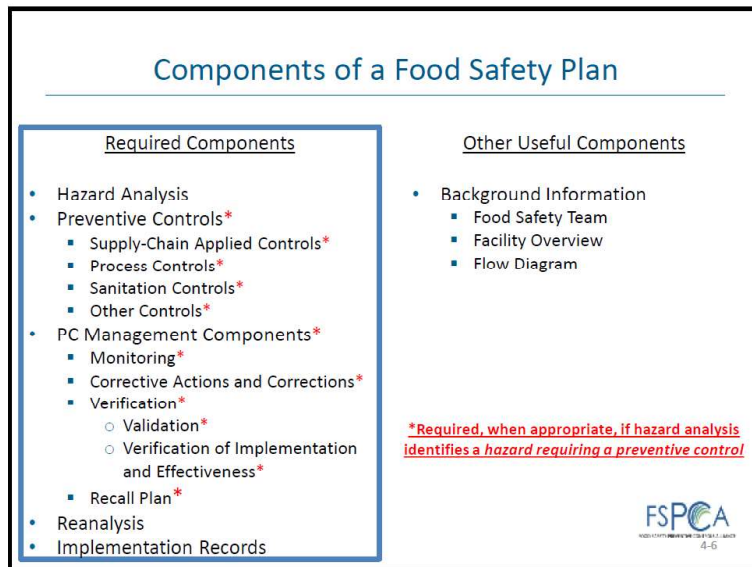
There are 7 primary components that must be included in the written food safety plan. These include the hazard analysis, preventive controls, supply-chain program, recall plan, procedures for monitoring the implementation of preventive controls, corrective action procedures, and verification procedures. The plan is subject to the documentation requirements of Subpart F, which were summarized in Chapter 1 and highlighted in the participant's note to the right of the slide.

A reminder that Subpart F requires:

- Promptly making records available to FDA upon request
- Records kept as original records, true copies, or electronic records
- Contain actual values and observations
- Be accurate, indelible, and legible
- Be created concurrently with the activity being documented
- Be detailed as necessary
- Maintenance of records for 2 years after the date they were prepared

Records must include:

- Information adequate to identify the facility
- Date and time (if appropriate) of the time the activity was documented
- Signature or initials of person performing activity
- Identify of the product and lot code, where appropriate



Some facilities may not have a *hazard requiring a preventive control*. In that instance, only the hazard analysis, reanalysis, and limited implementation record section are required.

If a facility has a *hazard requiring a preventive control*, it must have a preventive control, management components for that preventive control and a recall plan. Not all management components are required for each type of preventive control. This is described thoroughly in later chapters, especially in Ch. 6.

Slide 6

The food safety plan has various components, which are summarized in the outlined box on the slide. These required components include: hazard analysis, preventive controls (including supply-chain-applied controls, process controls, sanitation controls, and/or other controls), components required to manage those controls (including monitoring, corrective actions and corrections, and verification activities such as validation and verification of implementation and effectiveness), a recall plan, and implementation records. Several of these components, which are denoted with an asterisk, are required as appropriate when a facility's hazard analysis determines there is a *hazard requiring a preventive control*.

While these are the required elements, the food safety plan should be thought of as a tool to help communicate the food safety system to employees, customers, and regulatory authorities. For this reason, it is recommended that additional background information be included in the food safety plan. This background information can provide helpful context to other components of the food safety plan. An industry good practice would be to include an overview of the facility, the members of the food safety team, description of the facility, and a diagram showing equipment within the facility. The next section describes a recommended way to organize this information so it can be used in a practical manner.

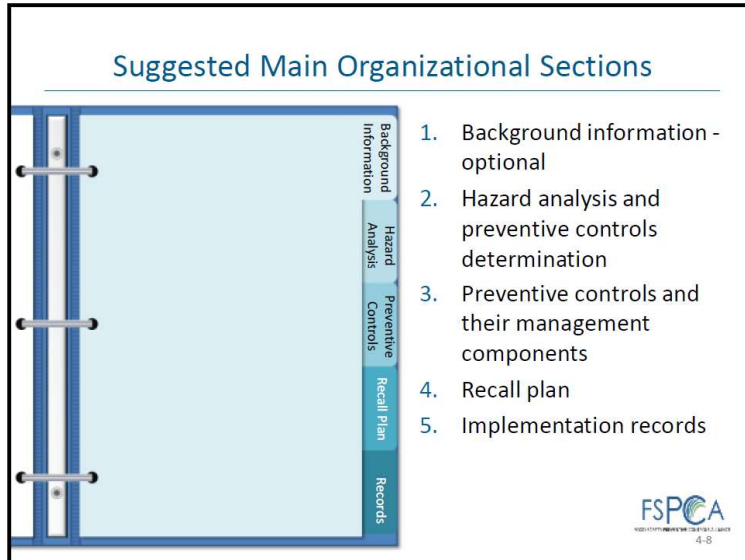


The signature of the owner, operator, or agent in charge of a facility is required because they are responsible for ensuring compliance with Subpart C.

Slide 7

There is flexibility in how to write and organize the food safety plan. This chapter will describe one option for combining the components into a single binder with different tabbed dividers for each section. While the organization is flexible, some of the components that must be included are not. For that reason, the required documentation for each section is summarized in the gray box on the right side of the slide. Later chapters cover the specific requirements for this documentation, such as what monitoring records must be included.

The required documentation for this slide describes that there is a specific requirement for the food safety plan itself. The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification. The facility has the option to store records offsite, as long as they are able to be retrieved within 24 hours. However, the food safety plan must be located on the same site as the facility at all times.

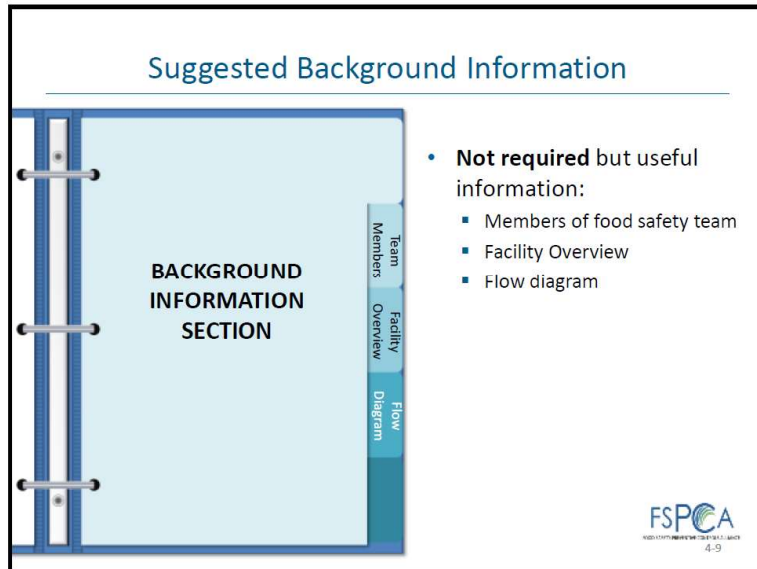


Slide 8

The example food safety plan format described in this chapter has 5 primary section divisions:

1. Background information, which is optional, but suggested
2. Hazard analysis, including preventive controls determination
3. Preventive controls with the associated management components
4. Recall plan
5. Implementation records

As a reminder, if the result of a facility's hazard analysis is that there are no *hazards requiring a preventive control*, then the facility's food safety plan will only be required to include the hazard analysis and implementation records.



Slide 9

The first section is the background information. Again, the *Preventive Controls for Animal Food* rule does not require this section, but it is recommended as a good industry practice. The inclusion of this chapter is helpful to communicate how the facility operates, which may be necessary when interacting with regulatory authorities, customers and employees.

Useful information to include in this section are the members of the food safety team and their role within the facility, a description of the facility, and a flow diagram showing equipment within the facility. Depending upon the facility, other information may be included if deemed helpful, such as an overview of the facility and a description of how product flows through the process. If a facility has multiple products with different processes, it may be appropriate to cover each of the different processes within the description.

Optional: List Food Safety Team Members

ABC Feed Mill

Food Safety Team Members

Name	Position
I.R. Charge*	Plant manager
F.S. Leader	Production supervisor
I.M. Quality	Quality supervisor
I.M. Fixer	Maintenance supervisor

*Preventive Controls Qualified Individual

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This is an example of a Food Safety Team member list that lists the individuals' names, and positions. The use of a food safety team is not a requirement. The PCQI may be the only one involved with development of the food safety plan in some facilities. Other facilities will utilize a team of individuals across departments. In this example, the food safety team includes the plant manager, production supervisor, quality supervisor, and maintenance supervisor.

In the provided example, the plant manager is the facility's PCQI, and she attended an FSCPA-recognized course. Instead of attending the course, the PCQI also could have been qualified through another equivalent curriculum or through job experience. The plant manager and all the other members of the food safety team are qualified individuals because they have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to their duties. Copies of their training records in animal food safety and personnel hygiene are in the implementation records section of the food safety plan for easy retrieval.

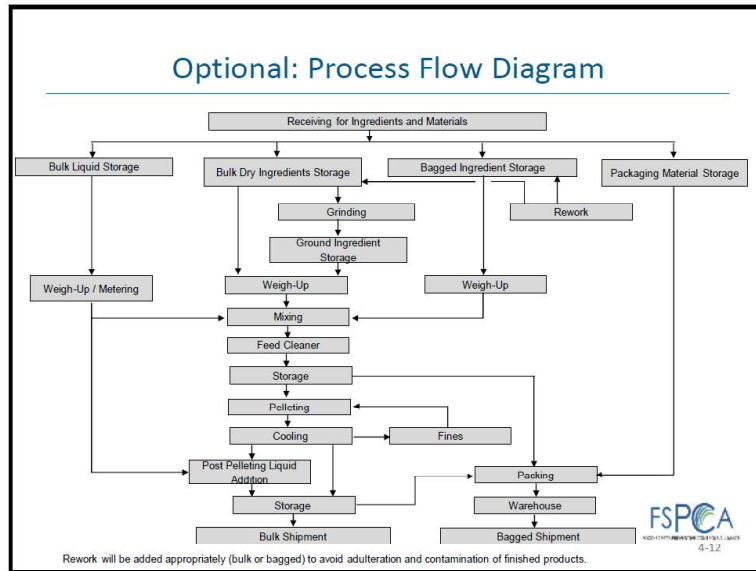
Optional: Facility Overview

- **Facility Description:** The facility was built in the 1960s and runs three shifts, 6 days per week. Approximate volume is between 350,000 and 500,000 tons annually.
- **Product Description:** Complete feeds for cattle, goats, poultry, sheep and swine at all ages. Feeds may be medicated or non-medicated. Feeds may be pelleted or mash.
- **Intended Use:** Feeds manufactured under this plan are to be fed as the sole ration to their intended species.
- **Animal Drugs:** Bacitracin methylene disalicylate, decoquinate, monensin, oxytetracycline, tylosin, virginiamycin

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Slide 11

The next section is a description of the facility, including a facility description, product description, intended use of the animal food, and medicated feed additives. In the case of ABC Feed Mill, the facility was built in the 1960s and operates 3 shifts and are run 6 days per week. The approximate volume of feed manufactured is between 350,000 and 500,000 tons annually. The facility manufactures complete animal foods for cattle, goats, poultry, sheep and swine at all ages. Animal food may be medicated or non-medicated and can be pelleted or mash. The animal foods are intended to be fed as a sole ration to their intended species, so there are no dry or liquid supplements manufactured in the facility. Finally, medicated feed additives are listed.

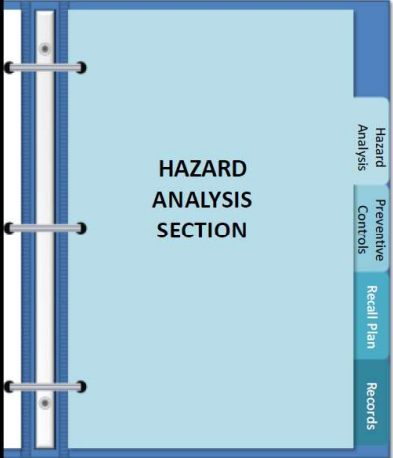


A relatively simple block flow diagram, such as the one in this slide, is very useful to quickly communicate how your facility manufactures, processes, packs, or holds animal food to employees, customers, and regulatory officials.

Slide 12

A process flow diagram is included next. This not the blueprint of the facility, but instead a block flow summarizing the ABC feed mill's manufacturing process from start to end. When flow diagrams are included, they can be as simple or complicated as desired to fit the needs of the facility. Flow diagrams are tools that can be used during the hazard identification process, so the flow diagrams should be accurate and as detailed as necessary.

Hazard Analysis – Required



The diagram shows a binder with a large light blue tab labeled 'HAZARD ANALYSIS SECTION'. To the right of this tab are four smaller tabs labeled 'Hazard Analysis', 'Preventive Controls', 'Recall Plan', and 'Records'. To the right of the binder, there is a list of bullet points and a box titled 'Required Documentation'.

- Drives decision making for determining and controlling hazards
 - Chapters 5 and 6

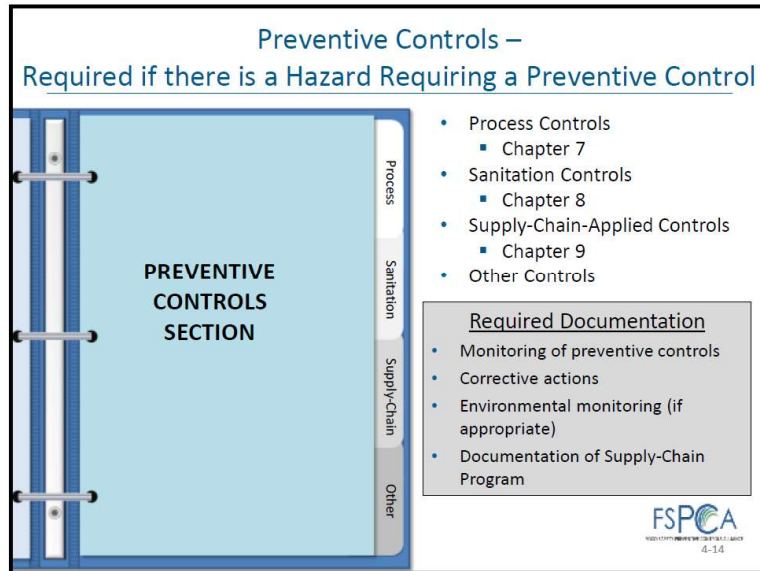
Required Documentation

- Hazard analysis
- Identification of the preventive controls
- Justification for not establishing a preventive control

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Slide 13

While the first segment of the food safety plan was an optional good industry practice, hazard analysis is required. The hazard analysis is used to evaluate known or reasonably foreseeable hazards and to establish appropriate preventive controls for *hazards requiring a preventive control*. The hazard analysis and preventive controls determination process will be described more fully in Chapter 5. The hazard analysis is required to be included in the documentation for the food safety plan, as well as the identification of preventive controls. In addition, if a *known or reasonably foreseeable hazards* exists but does not require a preventive control, justification for that determination must be included.

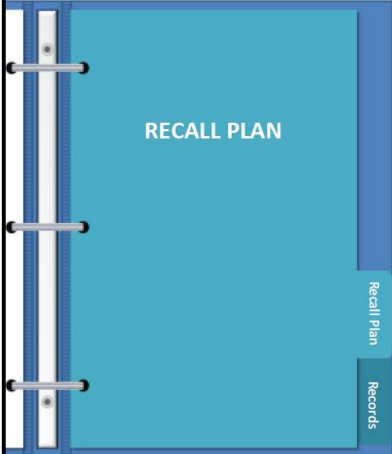


Slide 14

If there are any *hazards requiring a preventive control* identified in the hazard analysis, the preventive controls section is required in the food safety plan. This curriculum covers controls by their potential types: Process Controls as discussed in Chapter 7, Sanitation Controls as described in Chapter 8, and Supply-Chain-Applied Controls as described in Chapter 9. There is also a category for Other Controls. Other controls are a type of preventive controls that do not fit the definition of process, sanitation, or supply-chain-applied controls. Other controls may include hygiene training or other current good manufacturing practices. This course will not cover other controls in-depth; however, they are a type of preventive control so the requirements that apply to preventive controls also apply to them.

The preventive controls section of the food safety plan has many requirements for documentation. For example, records must be established and maintained for the management components used to ensure the effectiveness of the preventive controls, such as monitoring and corrective actions and corrections. In addition, the Supply-Chain Program section of the rule has specific recordkeeping requirements, which will be described more fully in Chapter 9.

Recall Plan –
Required if there is a Hazard Requiring a Preventive Control



- Describes what to do if preventive controls fail
 - Chapter 10

Required Documentation

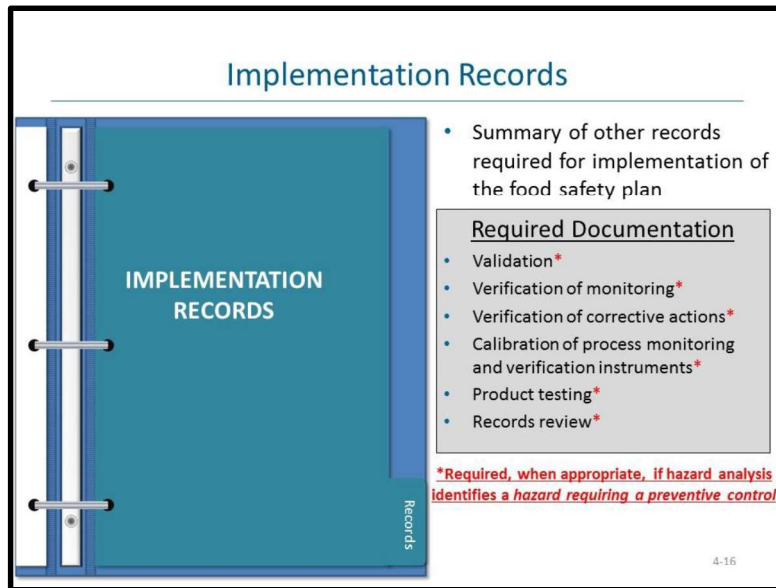
- Procedures that describe the steps to perform:
 - Direct notification of customers
 - Notification of the public
 - Effectiveness checks
 - Appropriate disposal of recalled animal food

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A recall plan is only required if a facility has a *hazard requiring a preventive control*. However, it is a useful component and all facilities should consider implementing such a plan, even if the facility is not required to implement preventive controls.

Slide 15

If a facility has identified a *hazard requiring a preventive control*, a recall plan for the animal food associated with the hazard is required. The recall plan describes the facility's course of action if a preventive control fails and contaminated product is distributed. The recall plan must include procedures for direct notification of customers, notification of the public, effectiveness checks to ensure the recall was successful in the facility retrieving the contaminated product from the marketplace, and appropriate disposal of the recalled animal food. These procedures are discussed in Chapter 10.



While implementation records for these components are required, they do not necessarily need to be part of the food safety plan in this format. For example, this section may have examples of blank records and a listing of their storage location. The actual records may be maintained in various files or forms.

Slide 16

Finally, the rule requires that certain records be kept and maintained by the facility. These do not have to be kept in one location. However, a section of implementation records in the food safety plan may be helpful to organize all other records necessary for the food safety plan. Required documentation includes validation of a preventive control, if required, verification of monitoring and corrective action, calibration of process monitoring and verification instruments, product testing, records review, and records that document applicable training for the PCQI and qualified auditor. While this example maintains copies of the training records within the binder itself, these records may be located in personnel files or other locations as long as they may be retrieved promptly upon request.

A list of all the records that are required to document implementation of the food safety plan can be found in 21 CFR 507.55: Implementation Records. Refer to the *Preventive Controls for Animal* rule in Appendix 1 for further information. This section of the regulation does NOT establish any new record-keeping requirements. Instead, it provides just a quick-view reference for people to find a summary of all the records required under subpart C to demonstrate implementation of the food safety plan.

21 CFR 507.50 Reanalysis

- (a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.
- (b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:
 - (1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
 - (2) Whenever you become aware of new information about potential hazards associated with the animal food;
 - (3) Whenever appropriate after an unanticipated animal food safety problem with § 507.42(b); and
 - (4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.



Slide 17

In addition to the requirements of what must be documented within a food safety plan, the *Preventive Controls for Animal Food* rule also describes the circumstances in which the food safety plan must be reanalyzed. At a minimum, the food safety plan must be reanalyzed at least every 3 years. The food safety plan may need to be reanalyzed more frequently if: significant changes occur to the activities conducted at the facility, the facility becomes aware of new information about potential hazards associated with the type of animal food it makes, or when the facility finds that a preventive control, combination of preventive controls, or the food safety plan is ineffective.

21 CFR 507.50 Reanalysis

- (c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified;
 - (1) Before any change in activities (including any change in preventive control) at the facility is operative; or,
 - (2) When necessary to demonstrate the control measures can be implemented as designed:
 - (i) Within 90 calendar days after production of the applicable animal food first begins; or
 - (ii) Within a reasonable timeframe, provided that the Preventive Controls Qualified Individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.

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Slide 18

If reanalysis determines a change in or addition of preventive controls is appropriate, the validation of those preventive controls must occur:

- 1) Before a change in activities at the facility is operative; or
- 2) When necessary to demonstrate the control measures can be implemented as designed:
 - a. Within 90 calendar days after production of the applicable animal food first begins; or
 - b. Within a reasonable timeframe, as long as the PCQI provides written justification for exceeding 90 calendar days.

The Preamble to the *Preventive Controls for Animal Food* rule gives more information regarding the requirement for when the validation of preventive controls must occur after reanalysis.

The Preamble states, "...if you decide to make a change, you should conduct a reanalysis before you make that change if there is potential for that change to create or increase a hazard; a reanalysis that results in changes to preventive controls should be completed and the preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, before changes in activities to produce animal food using a new preventive control are put into operation. However, we acknowledge that it may be necessary to produce product to demonstrate a revised preventive control can be implemented appropriately, and provide for an extended timeframe to make this assessment." See Preamble Response 378.

21 CFR 507.50 Reanalysis

- (d) You must revise the written food safety plan if a significant change in the activities conducted as your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.
- (e) A Preventive Controls Qualified Individual must perform (or oversee) the reanalysis.
- (f) You must conduct a reanalysis of the food safety plan when FDA determines it necessary to respond to new hazards and developments in scientific understanding.



Slide 19

The food safety plan must also be revised if a significant change in activities conducted at the facility creates a reasonable potential for a new hazard or a significant increase occurred for a previously identified hazard. If no changes to the food safety plan were deemed necessary during the reanalysis, that determination must be documented.

Any reanalysis of the food safety plan is to be performed or overseen by the PCQI.

Although the reanalysis schedule is typically set by the facility, the facility may have to conduct a reanalysis if the FDA determines that reanalysis is required to respond to new hazards and developments in scientific understanding that may affect the process of producing a safe animal food.

Food Safety Plan Reanalysis

- A food safety system changes with time.
- Periodic reanalysis is needed to verify that the whole system works.
- Required:
 - At least every three (3) years
 - New information becomes available about potential hazards associated with the food
 - Corrective action and correction
 - Preventive control ineffective
 - Significant change in product or process



Examples of a significant change in product or process are listed here. There are other times when reanalysis is warranted more frequently, and those examples are given throughout the curriculum.

These include:

- New information becomes available about potential hazards associated with the food (Ch. 4)
- Unanticipated problem (Ch. 7)
- Preventive control is ineffective (Ch. 8)

Slide 20

To summarize, the food safety system changes over time, so periodic reanalysis of the food safety plan is required to verify that the whole system, or components of the system, works. This reanalysis must occur at a minimum of every 3 years, but must occur more often if there is a significant change in the product or process, new information becomes available about potential hazards associated with the animal food, there is an unanticipated problem, or ineffectiveness of a preventive control. For example, if pathogens begin to become resistant to a specific type of sanitizer, it may be appropriate to reanalyze the sanitation controls in the food safety plan.

Examples of significant changes that may warrant food safety plan reanalysis include if there are changes in ingredients or suppliers, changes in product or process, new scientific information on hazards or control measures relevant to the product are found, or there are newly created distribution or consumer handling procedures. For example, repeated use of a correction suggests that the food safety plan should be reanalyzed.

Reanalysis should include verifying that the hazard analysis is still accurate and that the required documentation is appropriate.

Food Safety Plan Overview Summary

- A written food safety plan is required to include:
 - Hazard analysis
 - Implementation records
- If hazard analysis determines there is a *hazard requiring a preventive control*, the food safety plan must also include:
 - Preventive controls and their management components
 - Recall plan
- The format is flexible to meet the needs of the facility.
- The food safety plan must be reanalyzed at least every 3 years or more frequently, as appropriate.



Slide 21

In summary, the written food safety plan must include the hazard analysis, preventive controls and their management components, a recall plan, and implementation records. It is also suggested that background information be included about the facility, people, products, and processes to help describe the facility's food safety system. The format of the food safety plan is flexible to meet the needs of the organization, but the content of the food safety plan and its associated records must meet the *Preventive Controls for Animal Food* rule's requirements. Finally, the food safety plan must be analyzed at least every 3 years, but may need to be analyzed more frequently as required.