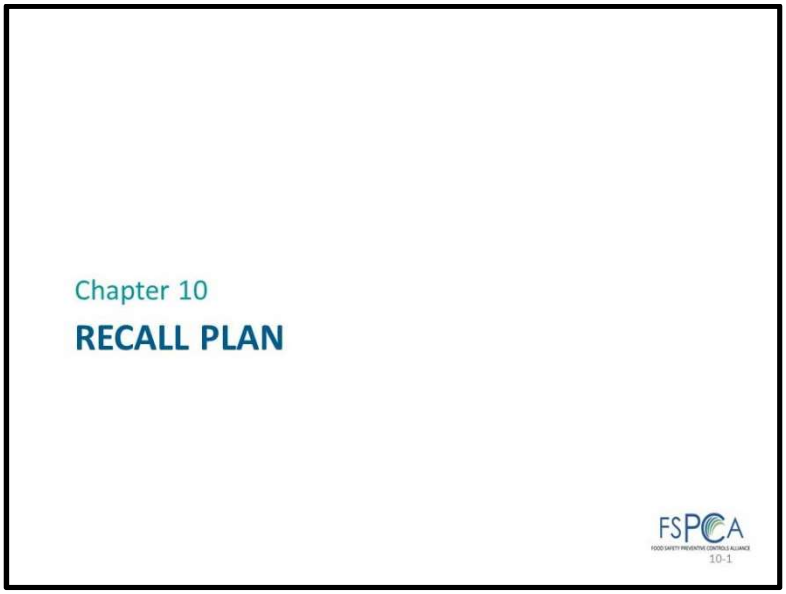
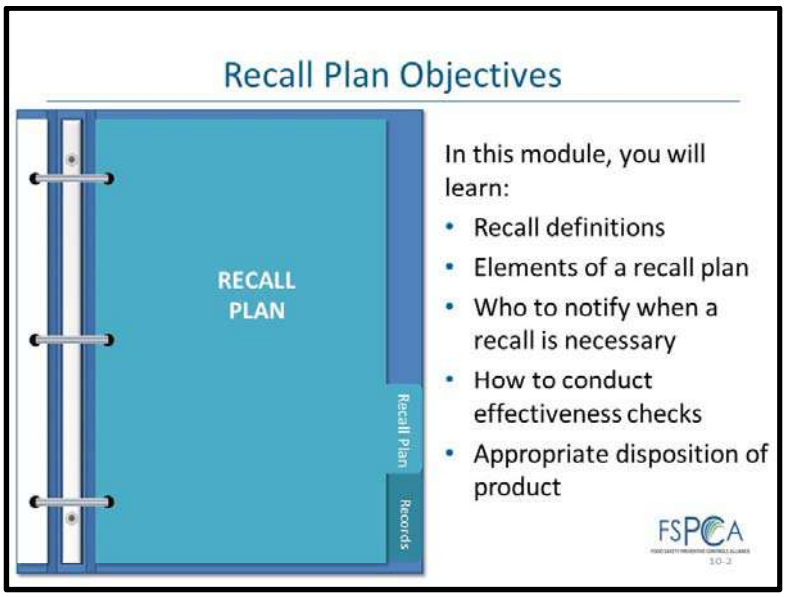
CHAPTER 10. Recall Plan



Slide 1

The *Preventive Controls for Animal Food* rule requires the development of a written Recall Plan when a hazard analysis identifies a *hazard requiring a preventive control*.

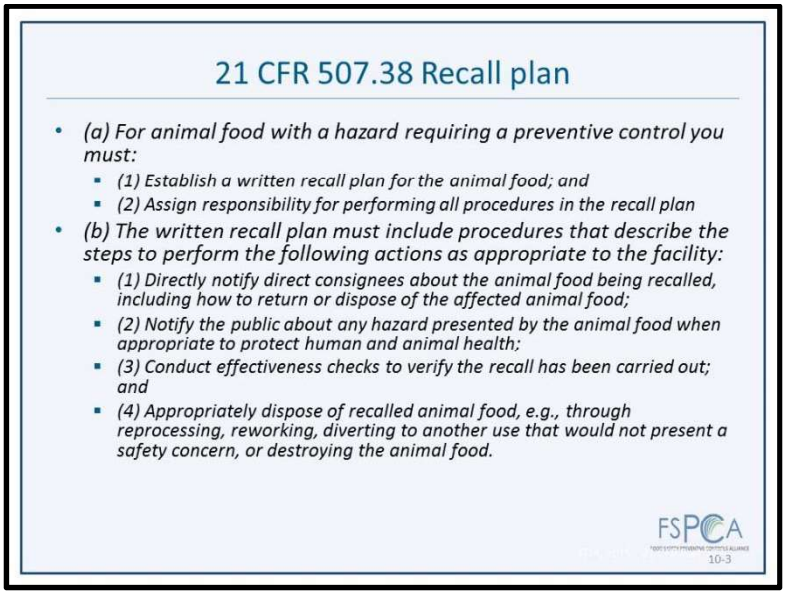


Note that this chapter describes the requirements of a recall plan according to the *Preventive Controls for Animal Food* rule and some additional good industry practices. This chapter does not cover all the FDA requirements regarding recall situations.

An effective recall plan can reduce the financial impact for the company by facilitating rapid retrieval of an adulterated product. An effective recall plan can also reduce the impact of an animal food safety event.

Slide 2

This module reviews definitions of recall classes, required elements of a Recall Plan, who to notify when a recall is necessary, how to conduct effectiveness checks, and methods that can be used to dispose of affected product.



Slide 3

The rule requires that a facility that identifies a *hazard requiring a preventive control* must establish a written recall plan and assign responsibility for performing all the procedures in the recall plan. The written recall plan must describe actions as appropriate to conduct a recall. The actions required include:

- Direct notification of consignees about animal food that is being recalled and how to return or dispose of the animal food.
- Notification of the public about any hazard present in animal food to protect human and animal health, as appropriate.
- Conduct effectiveness checks with customers who received recalled product, which may include warehouses, distributors, or animal feeders, to verify that all affected customers have been notified.
- Disposition of recalled animal food through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food, as appropriate.

Public press releases are required for Class 1 recalls and sometimes for Class 2 recalls when there is a threat to public health of humans or animals. Decisions regarding when notification is necessary can be determined through discussions with FDA.

FDA has the authority to mandate a recall in Class I situations, but typically, a company voluntarily issues the recall notice. The mandatory recall authority is outlined in 21 CFR 7.40, which provides guidance on the policy, procedures, and industry responsibilities for conducting a mandatory recall.

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Recalls are actions taken by an establishment to remove an adulterated, misbranded, or violative product from the market. If a company withdraws a product for quality issues or the product has not entered commerce, the actions are not usually considered a recall.

Three classes of recalls are defined based on the potential health effects.

- A Class I recall is the most serious and involves product that has a reasonable probability of causing serious injury, illness, or death.
- Class II recalls may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recalls are not likely to cause adverse health consequences, but are still in violation of the law.

Typically, a company voluntarily conducts a product recall, either on their own accord or at the request of FDA or a state. However, the Food Safety Modernization Act grants FDA mandatory recall authority to require a Class I recall, if necessary.

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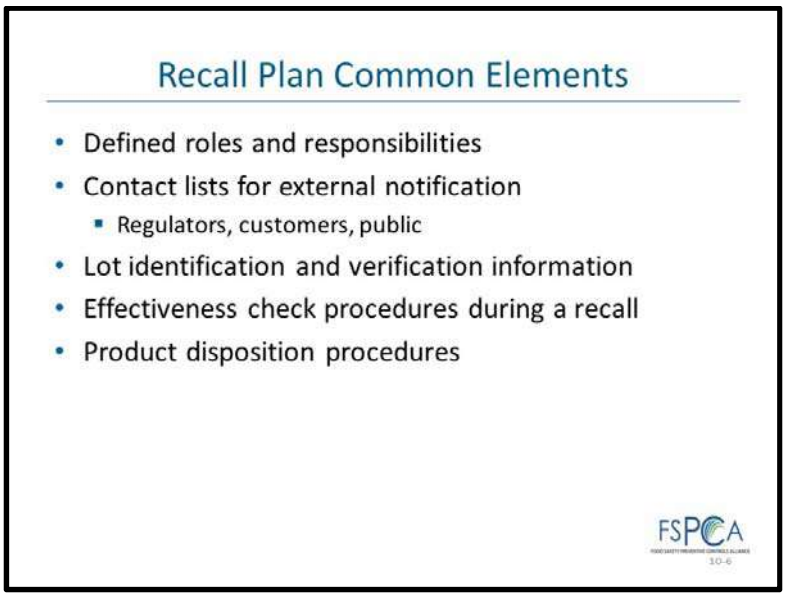
A Recall Plan must be written and in place before a recall occurs to ensure that actions taken to recall an animal food are conducted efficiently and in a timely manner. A rapid response is especially important for Class I and Class II recalls for which public health is at risk.

The written Recall Plan must include procedures that describe the steps to take and assign responsibility for those steps. Some people can be assigned to multiple tasks, but their role should be defined in the Recall Plan to support a quick response. The required procedures include those outlined in Slide 3: the notification of customers, notification of the public, effectiveness checks, and the appropriate disposition of animal food.

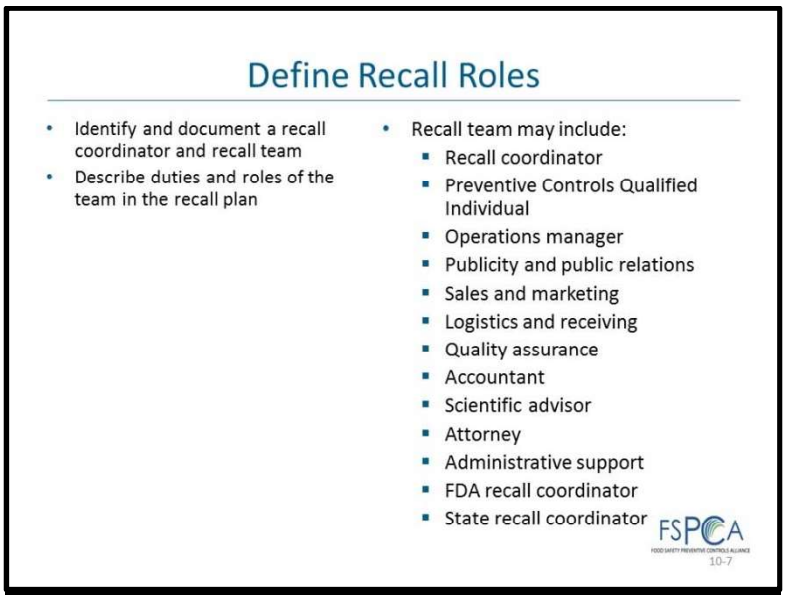


Slide 6

The rule is flexible and does not specify how a facility should carry out recall procedures, just that those procedures must be written. Examples of good industry practices that may be included in the Recall Plan are:

- Predefined roles and responsibilities;
- Procedures to determine if a recall is needed;
- Contact lists for external notification of regulators, customers, and the public;
- Lot identification descriptions;
- Effectiveness check procedures to be used during a recall;
- Forms to record information; and
- Draft notices to complete in the event of a recall.

A brief discussion of these common industry practices is outlined next.



The recall coordinator should be someone who can devote full attention to the recall and keeping things organized.

Small companies may not have enough people to assign different people to each role.

Slide 7

The owner, operator, or agent in charge of a facility is accountable for the safety of the animal food, but this responsibility for overseeing recalls may be carried out by the *Preventive Controls Qualified Individual*. A recall coordinator may or may not be the PCQI. The coordinator, and when appropriate a recall team, are typically identified in the Recall Plan. The recall coordinator generally has the following duties:

- Directs all product recalls
- Directs the recall team and coordinates all actions and communications
- Ensures that all appropriate documentation relating to the manufacture and shipment of the affected product is collected; e. g., processing records, laboratory testing records, ingredient batch sheets, inventory reports, shipping manifests, depending on the incident
- Determines (e.g., from inventory management and shipping records) exact location and quantity of affected product involved in the recall
- Reports the status, findings and recommendations related to all product recall situations to senior management if they are not part of the recall team
- Notifies all pertinent regulatory agencies
- Maintains the establishment's written policy, Recall Plan, and all associated recall activities

The recall team should include all functions necessary to collect accurate and complete information. For example, production, shipping, quality assurance, sales and administrative personnel should be considered as members of the recall team. If the firm has multiple locations, the team may include corporate team members from different departments (e.g., safety, quality assurance, distribution, etc.). Each recall team member should have clearly defined roles.

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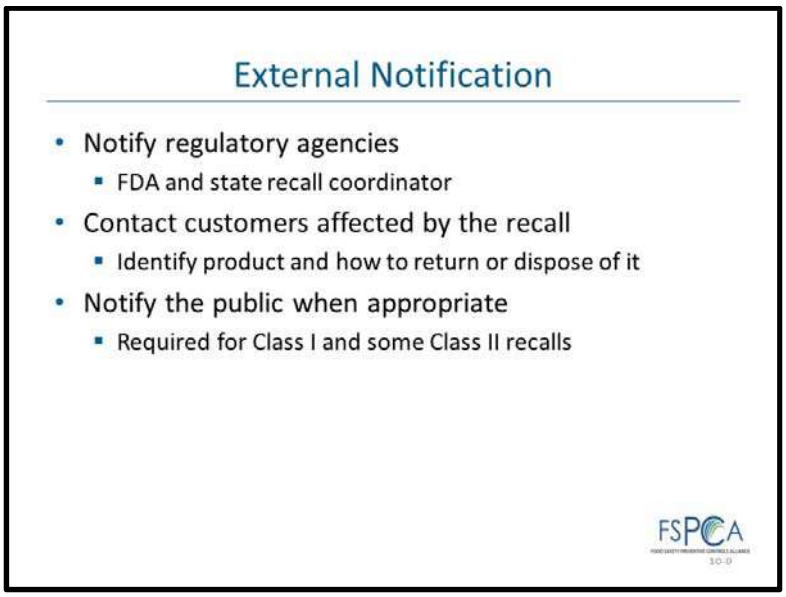
The Recall Plan should define each step of the recall process and clearly describe what needs to be done and who is responsible for carrying out each task. Knowing this ahead of time and conducting mock recalls reduces confusion and helps to support an organized response. As an industry good practice, a mock recall may be helpful to conduct on an annual or semi-annual basis. The use of mock recalls will be discussed more thoroughly later in this chapter.

In the recall plan, all responsibilities should be clearly defined, such as who will initiate the recall and who will notify external customers. Clear documentation helps to define the extent of the recall. While several people may be involved in gathering different types of documents, compiling the information and data gathered ultimately should be done by one individual to ensure that a complete picture of the situation is available. Assign responsibility for each of the types of documents needed to ensure that everything is completed.

When recalls occur, some of the affected product may still be in the company's control. Other product may be in transit to or be in possession of customers. In addition to notifying customers, assign responsibility and define procedures for securing inventory that is still within the control of the company to avoid inadvertently shipping product that would be subject to a recall.



If a recall is deemed appropriate, the firm should contact the recall coordinator from their FDA District Office. This information is available from the FDA website and may be beneficial to include in your recall plan.

The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is reasonable probability that an animal food will cause serious adverse health consequences. Facilities must report food safety issues to FDA within 24 hours of determining that the issue presents serious health consequences. The RFR is also useful for investigating information on animal foods that have been reported.

FDA posts recall notices on their website. Model recall notices are also available, which may be used to create a draft recall notice for a facility's Recall Plan.

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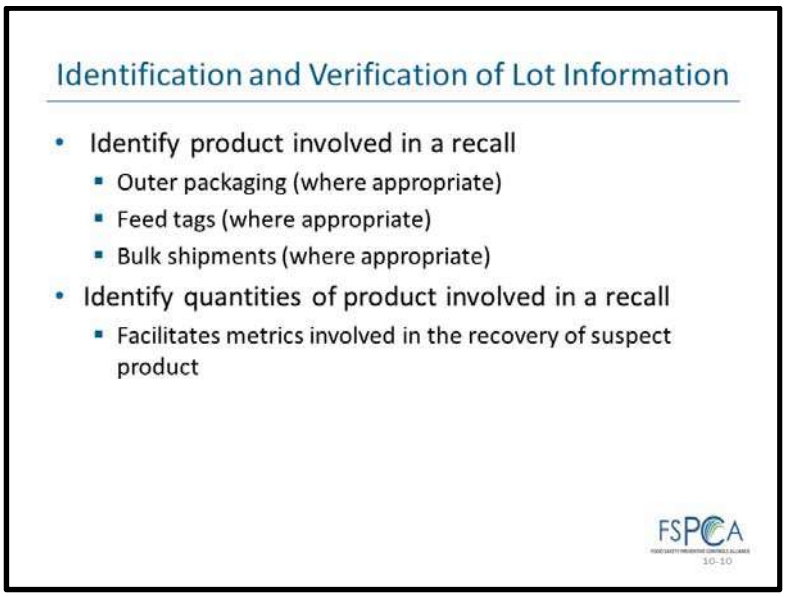
When it is determined that a recall is necessary, notify the appropriate regulatory agencies. In addition to notifying the FDA, many states have recall coordinators. It is useful to include their contact information in a Recall Plan.

The Recall Plan must include procedures for notification of outside customers/consignees who received product. Customers should be informed of the type of product, quantities of affected product they received, dates product was shipped and reason for the recall. Also tell customers to immediately put product on hold. Once information is gathered, product disposition will be determined, as well as effectiveness of the recall effort.

A press release is required for all Class I recalls, and in situations when the facility is not able to contact all of their direct consignees. In addition, a facility may choose to issue a press release with some Class II recalls. While a detailed press release cannot be developed until an incident occurs, a Recall Plan can include templates that describe the information that would be inserted and should identify where to send a press release if this is necessary. FDA policy gives the recalling firm the first opportunity to prepare and issue publicity concerning its recall. During a recall situation, the facility should work with the FDA to develop and approve the press release. The Agency has model press release examples available. If the FDA believes it to be necessary, the agency may issue its own press release announcing a firm's recall.

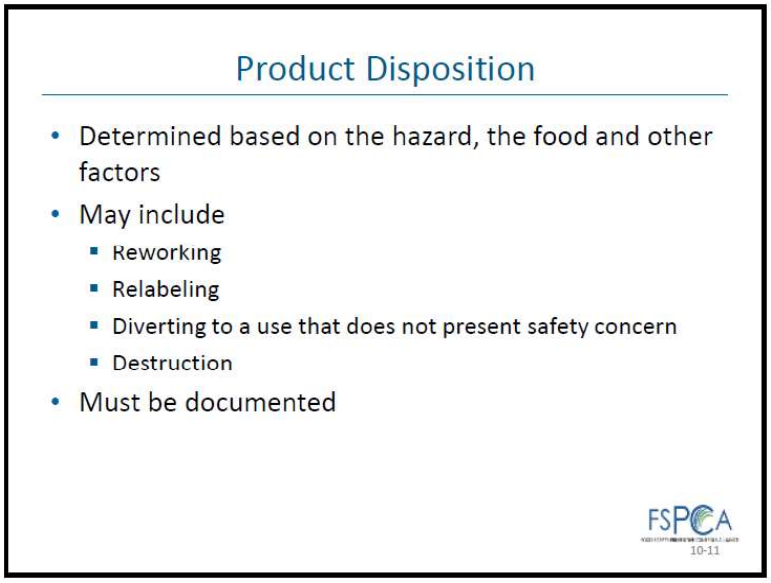


Slide 10

Lots involved in a recall must be accurately identified. The method of identification may vary based on the type of animal food being produced and its method of production. For example, some lots may be broken by individual mixed batch, by truckload of bulk shipment, or by date of manufacture. For this reason, a good industry practice includes breaking the manufacturing of a product into small lots, when appropriate, to minimize the volume of product requiring recall.

Lots may be identified on outer packaging, on feed tags, or even on bulk shipment records. Regardless of how the product is identified, the information should be easily understood by all the stakeholders that receive this information during a recall investigation. Unclear or poorly identified lots hamper the effectiveness of any recall effort and increase the amount of time and resources needed to complete the recall. Lot records should be rapidly accessible.

All information should be cross checked for accuracy. Incomplete or erroneous information causes confusion and delays in transmitting information. Lack of organization can slow down the process. Accurate information is needed for government agencies and the facility to conduct a thorough and efficient recall.



Slide 11

The Recall Plan must include procedures that describe the steps taken to determine the appropriate disposition of the recalled product. Depending upon the hazard and the animal food, sometimes a product can be reconditioned to make it suitable for use as animal food. Diverting the animal food to another use may be an option as long as it does not create an animal food safety issue. For example, it may be possible for a sheep feed that contains a level of copper toxic to sheep to be fed to beef cattle, when appropriate, because beef cattle are not as sensitive to copper toxicity as sheep. Destruction of the animal food is the final option, and is sometime necessary. However, destruction should occur in a way to ensure the animal food is not used for an unintended purpose. For example, animal food that is packaged in bags should have the bags sliced open prior to composting to prevent unintended use for another animal.

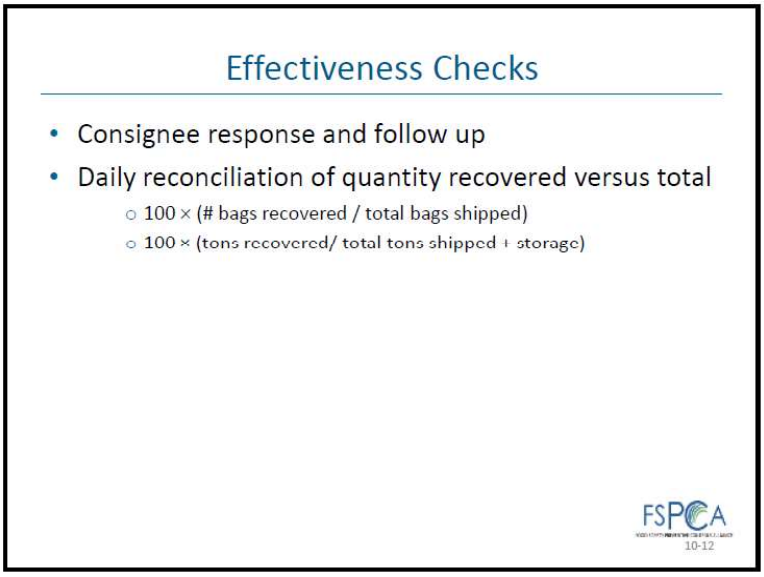
If an animal food is recalled due to a safety concern, a facility can decide to reprocess if they want to recondition the recalled animal food. The facility needs to inform FDA and State authorities and provide their reconditioning proposal, which should follow FDA Compliance Policy Guide 675.200 *Diversion of Adulterated Food to Acceptable Animal Feed Use*. This document can be found on the FDA website, www.fda.gov, under the Animal & Veterinary tab by selecting the Guidance, Compliance and Enforcement link. In addition, animal food being reworked must be handled in accordance with CGMP requirements for plant operations per 21 CFR 507.25.

The definition of *rework* "means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food."

Additional information about recalled product for industry can be found in the FDA GFI #235. The guidance on 21 CFR 507.25(a)(7) and 507.27(d)) may be particularly useful.

Procedures for product disposition need to consider both product that is in-house (and thus under the establishment's control), as well as product that is returned from customers. In some cases, the firm may direct customers to destroy product instead of returning it. Such situations may be described in the Recall Plan. In any case, a clear account of the quantity of product available and its ultimate disposition is needed to complete a recall.

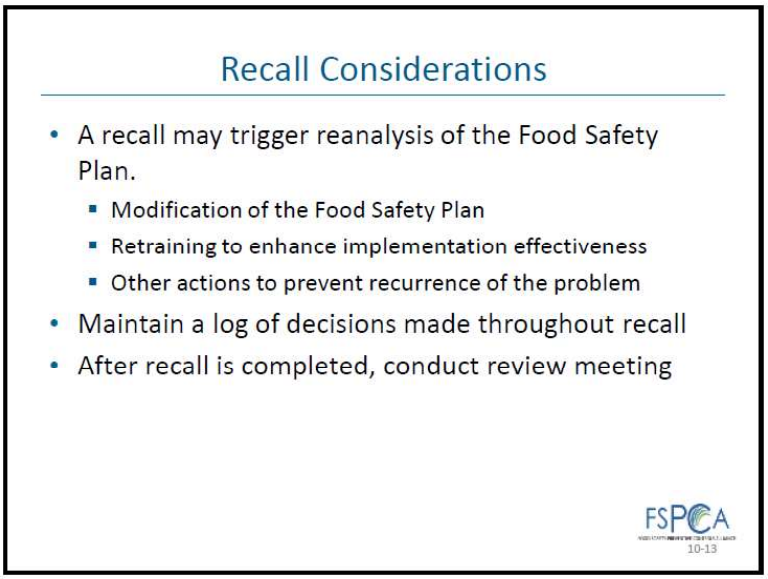
The method of disposition must be documented as part of this process.



Slide 12

The recalling establishment must determine whether its recall is progressing in a satisfactory manner. The firm has an obligation to conduct effectiveness checks as part of its recall process. These checks are used to verify that all affected customers were notified about a recall and have taken appropriate action. A Recall Plan should describe how effectiveness checks will be conducted during a recall. Most establishments follow up daily with customers via phone calls or email to ensure they are progressing in locating and segregating all affected material. In some cases, onsite assistance may be necessary at customer locations.

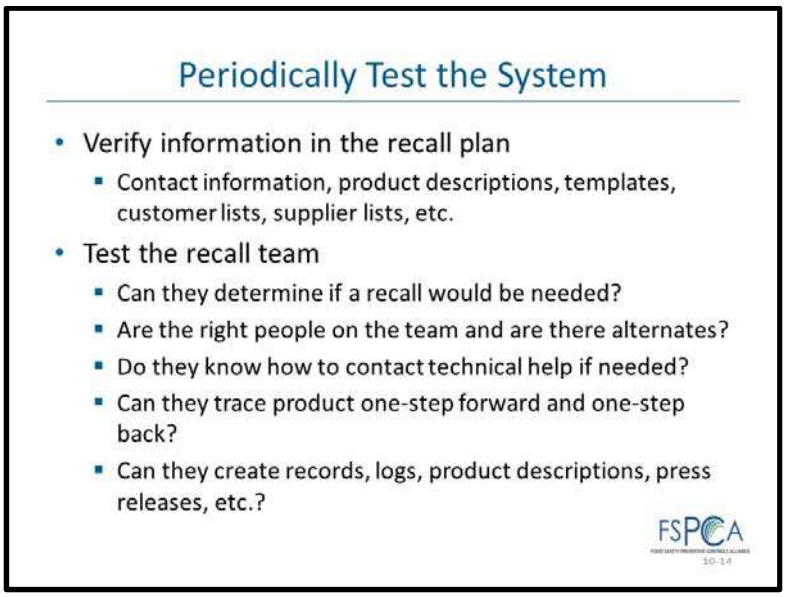
Some examples to evaluate the effectiveness of a recall include daily reconciliation of the volume of product recovered compared to the total quantity recalled. Calculations to quantify effectiveness may include either the number of bags or the number of tons recovered, or both.



Slide 13

A recall suggests that a preventive control, or combination of preventive controls, or the Food Safety Plan as a whole is ineffective. If this is the case, reanalysis of the Food Safety Plan is required (507.50(b)). In some cases, modification of the Food Safety Plan may be required. For example, if a new hazard is identified, the hazard analysis should be updated to include that hazard and preventive controls should be modified or added to ensure ongoing control. In other cases, the Food Safety Plan may be adequate, but implementation of the plan may need to be improved through enhanced training, equipment upgrades or other relevant corrections. In any case, the animal food safety team should strive to determine the root cause of the problem and act quickly to take corrective actions, as appropriate.

Previous chapters described corrective actions that may be appropriate for different preventive controls, as well as the documentation requirements for corrective actions. Likewise, records of a recall should be maintained, including a log of ongoing decisions and activities, as well as a summary of the final recall review. There is a template at the end of this chapter that may be useful for a firm constructing a Recall Plan and the associated records to support these efforts.

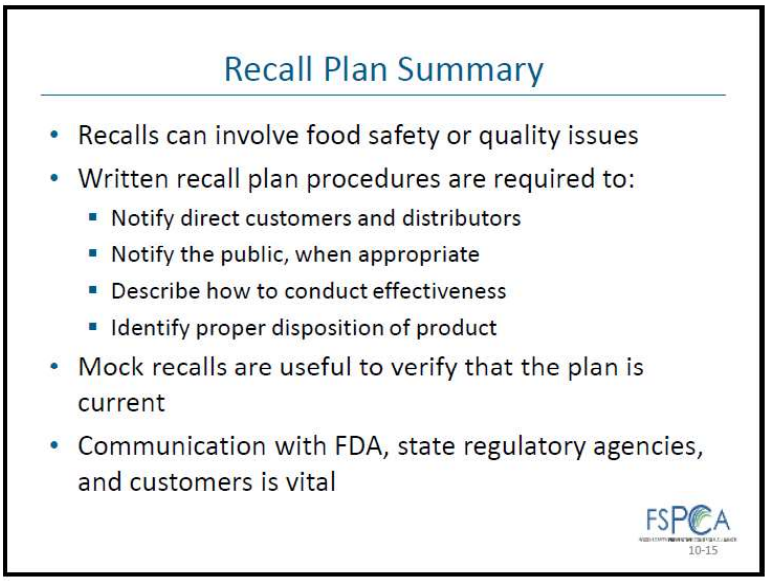


Slide 14

Once the recall plan is developed, it is important to periodically test the system to ensure that it will work if a recall is necessary. This is sometimes referred to as a "mock recall," which is used as an industry good practice. These mock recalls typically include verifying that the information in the recall plan is current, and testing the recall team to determine if they can do what is necessary should a recall occur. Tracing products and ingredients one-step forward and one-step back in the supply chain is a common element of a mock recall; however, actual customers and suppliers are not typically contacted to avoid confusion.

Traceability checks are an important part of a mock recall. These checks determine how long it takes to identify where a specific lot of product was sent (one step forward) and to identify the source and lot code(s) of all ingredients used in the production lot (one step back). In addition, it is useful to test the recall team to see if they can determine if a recall is actually necessary, if they know who and how to contact for technical help if needed, if they can create the required documentation to perform a recall.

A test of the system can be performed over time (e.g., verifying contact information), but the importance of conducting mock recalls should not be overlooked.



Slide 15

A written Recall Plan enables rapid response to remove contaminated product from the marketplace if it contains a hazard that may cause illness or injury to humans or animals. A Recall Plan should define who to contact if a recall is necessary. Effectiveness checks are required when a recall occurs. Mock recalls are useful to ensure that the plan is current and that people understand their roles. A rapid and efficient response can reduce the number of animal and human illnesses and protect a business. Proper disposition of product is necessary, as is effective communication with FDA, state regulatory authorities, and customers.

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