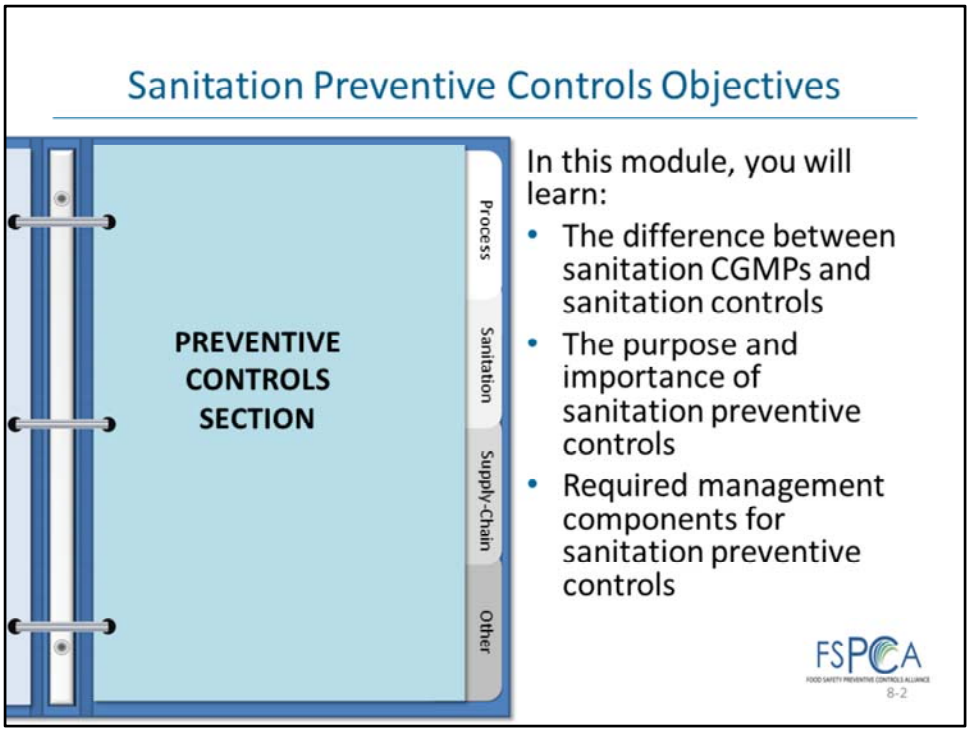
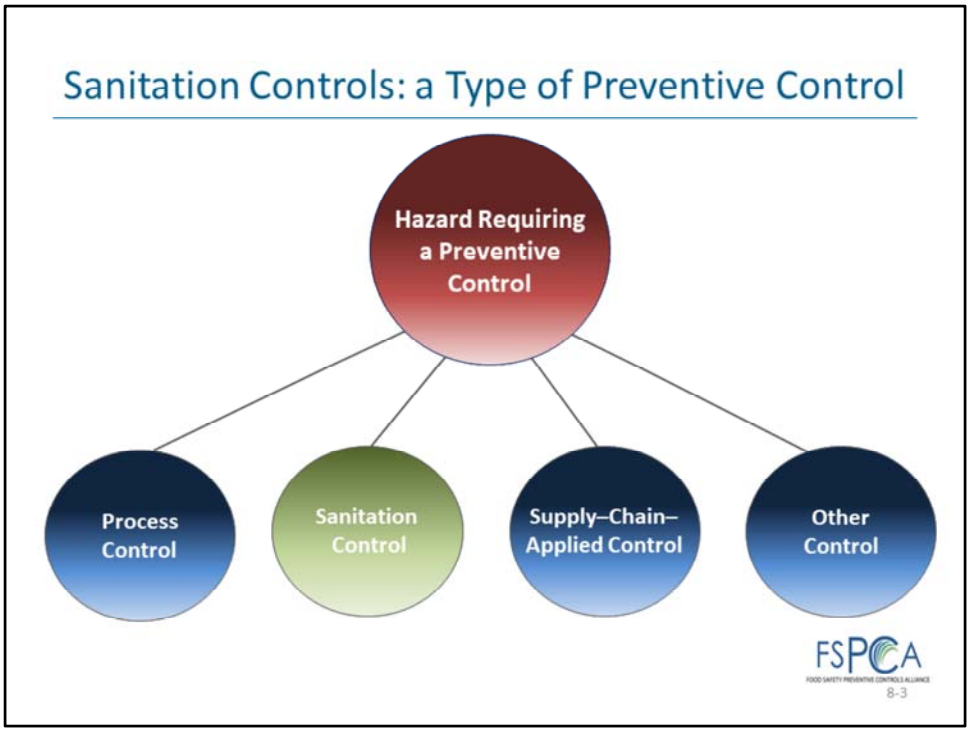
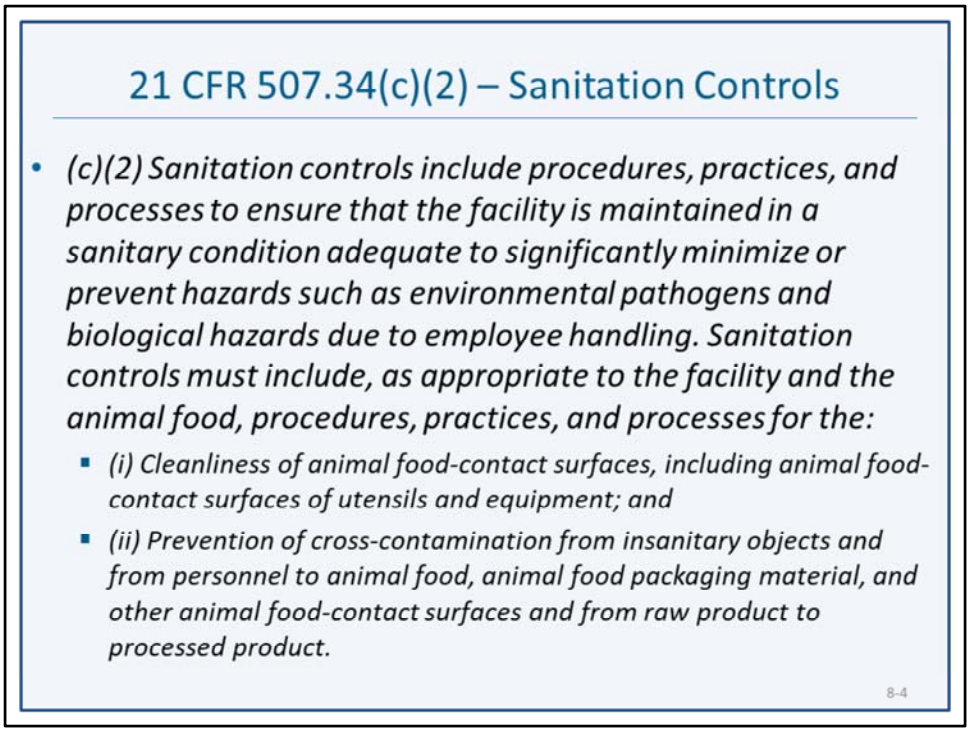
The next preventive control category to be discussed during this course is the sanitation controls.



The goals for this module are to describe 1) the difference between sanitation CGMPs and sanitation controls, 2) the purpose and importance of sanitation controls, and 3) the required management components for sanitation controls.



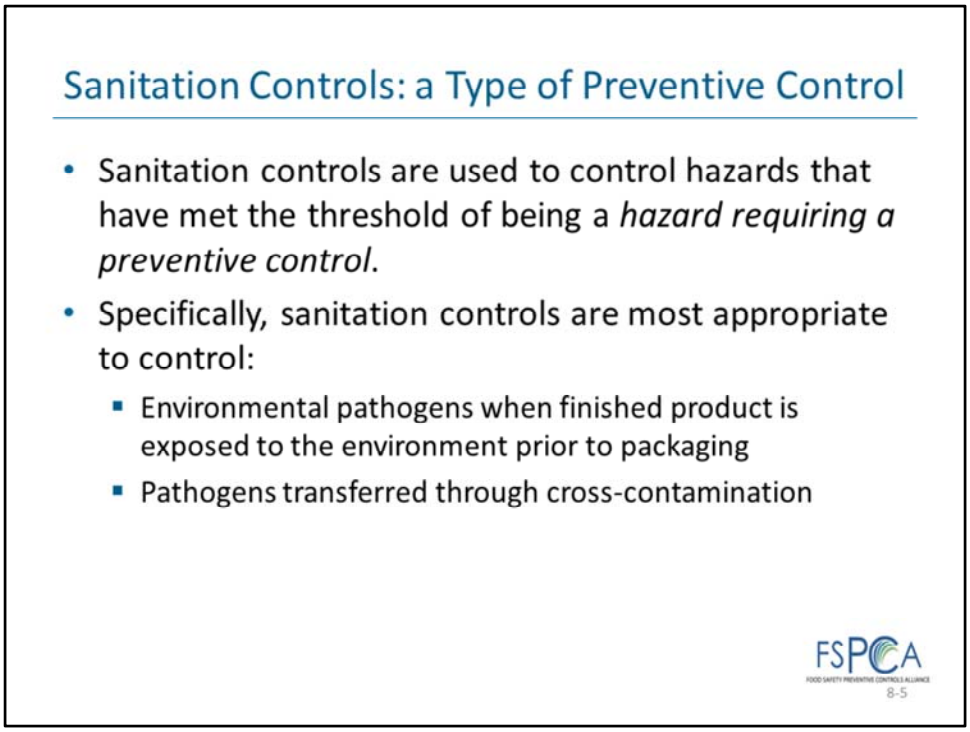
Chapter 7 described how preventive controls could be used to address hazards associated with a process step. The sanitation controls describe a more holistic approach, and are typically used to prevent cross-contamination of pathogens after a process control.



(Note that *environmental pathogen* is defined in 21 CFR 507.3 as, "a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic spore-forming bacteria.")

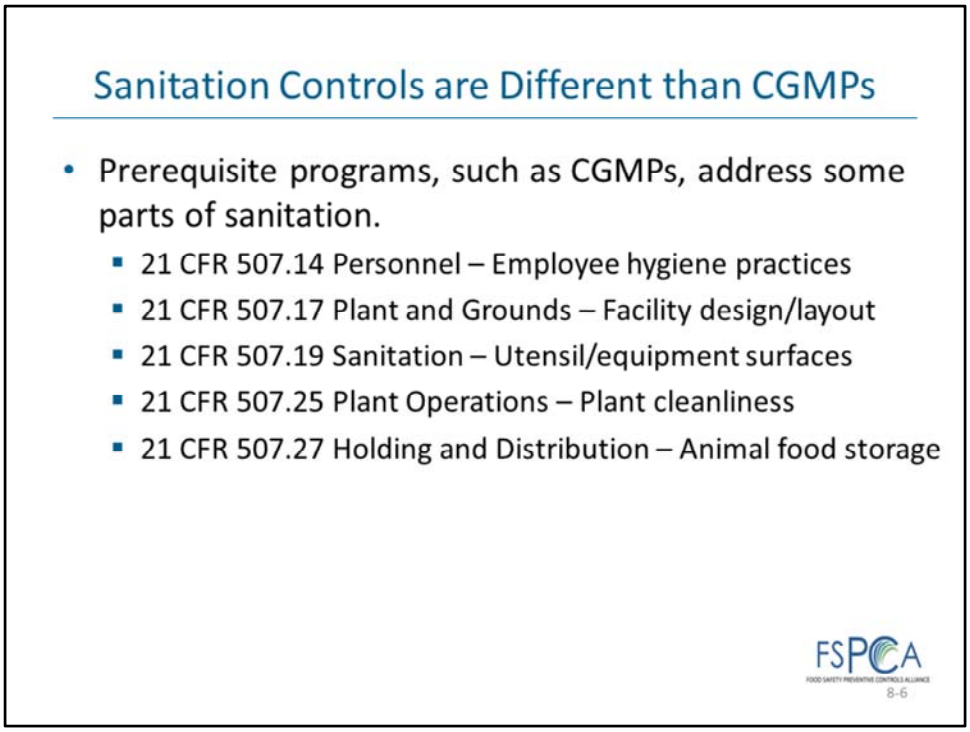
This slide is a continuation of the preventive controls section that we introduced in Chapter 7 during our discussions of process controls. The regulations for sanitation controls are listed in Part 507.34(c)(2), which can be found on the top of page 56346 in Appendix 1. In this curriculum, the term "sanitation preventive control" is used interchangeably with "sanitation control" and both terms have the meaning specified in 21 CFR 507.34(c)(2).
The regulation require activities to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling.
Sanitation controls must include, as appropriate:

- Cleanliness of animal food-contact surfaces, including utensils and equipment
- Prevention of cross-contamination from objects, personnel, and raw product



Sanitation controls are used to control biological hazards that have been identified as a *hazard requiring a preventive control.* Like all other hazards that meet this definition, the combination of severity and probability warrant the hazard's evaluation as requiring a sanitation control. The use of a sanitation control, in the sense of a preventive control, is different than the use of sanitation CGMPs.

Not all facilities will have sanitation controls. They are most appropriate to control environmental pathogens when finished product is exposed to the environment prior to packaging and to control pathogens transferred through cross-contamination. Because the primary undesirable microorganisms in animal food are *Salmonella* spp. and *Listeria monocytogenes*, most of this chapter will describe efforts to control those pathogens. If a facility does not have a biological hazard that requires a preventive control, it is unlikely a sanitation control would be required.



Sanitation controls are different than the CGMPs that address sanitation, but the two work together to establish a sound foundation for the animal food safety system. The considerations on the slide above are potential examples where CGMPs address sanitation and work to prevent cross-contamination. For instance, it is important for employees to understand that their actions can contribute to product contamination. Employees working in a raw product area subject to biological hazards should not work with a finished product without washing and sanitizing their hands, equipment, or utensils to avoid cross-contamination. Personal cleanliness is also important to prevent product contamination and is generally managed through CGMPs. Workers must wear clean and appropriate attire. For example, an employee who spills a potential chemical hazard, such as petroleum-based grease, on his or her clothing should take appropriate hygiene practices to prevent subsequent contamination to animal food.

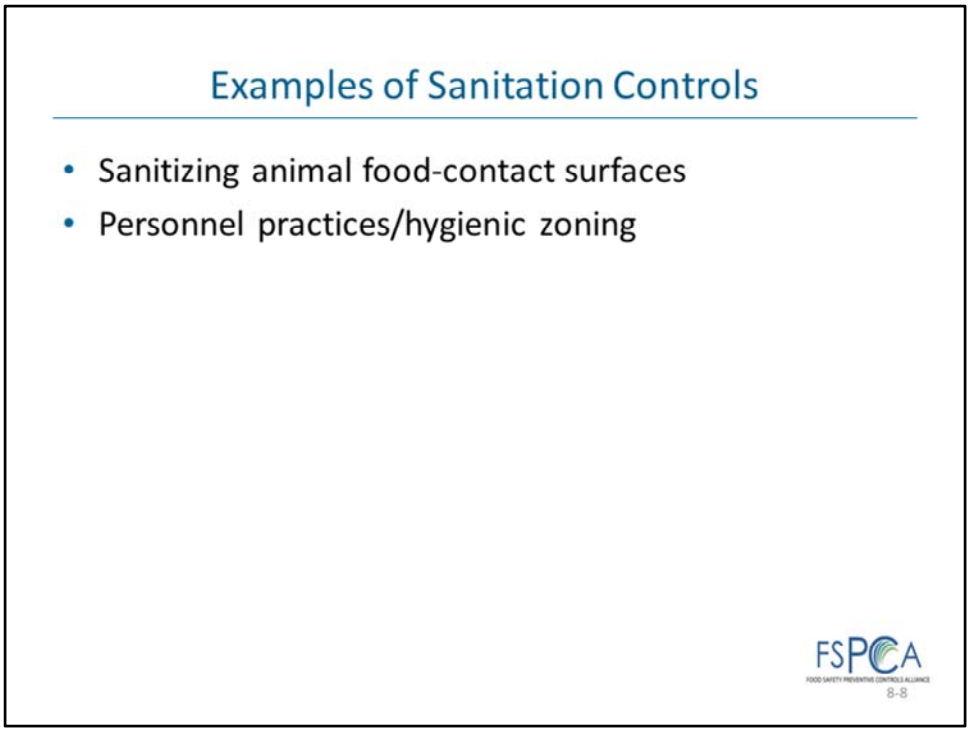
Plant design must prevent potential contamination of animal food, animal food-contact surfaces, and animal food packaging material by separating operations where contamination is likely to occur. This means separating raw product and unpackaged finished product subject to biological hazards to avoid contamination.

(An animal food contact surface is the area of equipment or utensils that comes into contact with animal food. For example, the inside of a conveyor or mixer is an animal food contact surface, while the outside of that equipment is not. In addition, the blade of a shovel used to move an ingredient is an animal food contact surface, while the handle is not.)

Lack of effective sanitation controls have contributed to major recalls of animal food. When a hazard analysis identifies a hazard requiring a sanitation control, the procedures, practices and processes used to manage these hazards must be developed and documented. As appropriate to the animal food, facility and the preventive control's role in the animal food safety system, sanitation controls may involve procedures to ensure the cleanliness of animal food-contact surfaces, including those of utensils and equipment. Sanitation controls may also involve procedures to significantly minimize or prevent microbial cross-contamination.

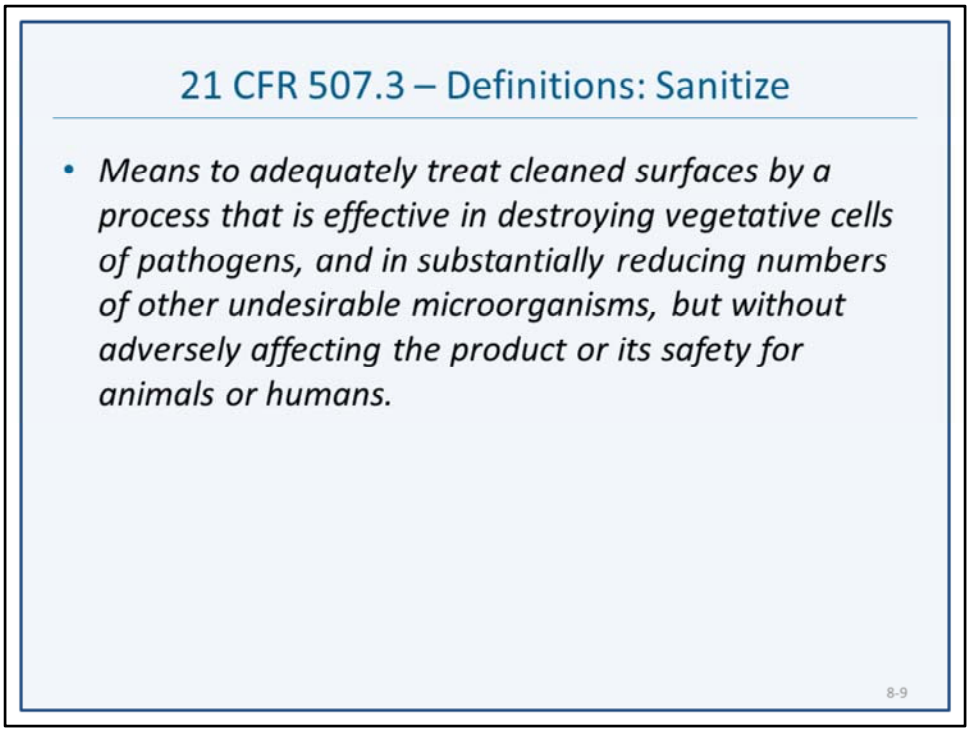
Preventing hazard transfer from insanitary objects (such as dirty equipment and environmental sources) and from personnel to animal food, to animal food packaging material, and to other animal food contact surfaces may be appropriate depending on the operation. Preventing transfer from raw material to finished product may also be appropriate in some situations (e.g., from raw material to finished product subject to biological hazard contamination).
Personnel can play a big role in preventing transfer of contamination. Animal food

safety and animal food hygiene training is required by the *Preventive Controls for Animal Food* rule. This can help employees to understand the important role they play in the animal food safety program.



(Other sanitation controls, such as dry or wet cleaning, may exist. The type of sanitation control depends upon the facility. There is additional discussion in the Preamble of the *Preventive Controls for Animal Food* rule regarding the role of wet cleaning. In many cases, dry cleaning is allowable and sufficient. In cases when wet cleaning is necessary, the water must not be a subsequent source of contamination of animal food.)

The types of appropriate sanitation controls depend upon the facility. Examples of potential sanitation controls include the sanitizing of animal food-contact surfaces and control of personnel practices, such as hygienic zoning. Before we can discuss these examples further, it is appropriate to visit the regulatory definition for *sanitize*.



(Note that 'sanitize,' as defined here, is different than the more generic term, 'sanitation.' The Preamble of the *Preventive Controls for Animal Food* rule describes this difference. Sanitation describes general cleaning practices, which are primarily encompassed in the CGMPs. Meanwhile, 'sanitize' or 'sanitizing' means the treating of cleaned surfaces as described in the definition. When used in this sense, these activities are typically sanitation controls.)

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

One of the examples of a sanitation control is the sanitizing of animal food surfaces – and this is Preventive Control #2 for ABC Pet Food Manufacturing Facility. Preventive Control #2 from this food safety plan is used as an example in the remainder of this chapter.

Sanitizing animal food contact surfaces is most appropriate when the destruction of microorganisms is required. Some facilities utilize steam systems for sanitizing, which clean and sanitize the surface in a single step. This meets the requirements of sanitizing. Notably, sanitation controls are typically more aggressive than routine sanitation procedures if an environmental pathogen has become established. For example, *L. monocytogenes* is exceedingly difficult to remove from a manufacturing facility once it is persisting. As such, more strenuous sanitizing may be appropriate to significantly minimize the hazard.

Regardless of the sanitizing manner, explicit details should be documented when developing surface sanitizing procedures. These details include the purpose of the activity, frequency, who is responsible for the activity, how the preventive control will be monitored, appropriate corrections or corrective actions (if necessary), verification of the preventive control activities, and appropriate records.

While sanitizing animal food contact surfaces may be used in some food facilities, it is not appropriate for all animal food manufacturing facilities to sanitize surfaces. In

fact, it is impractical or impossible in many facilities to sanitize the animal food-contact surfaces. However, sanitizing animal food contact surfaces is relevant when the hazard analysis process identifies that a *hazard requiring a preventive control* is to be controlled by a sanitation control.

Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Pet Food Example

SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.
Frequency: Before operations begin and at the end of daily production
Who: Sanitation team member
Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet
Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.
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: Daily Sanitation Sheet
Verification: Supervisor (daily) and PCQI (within 7 working days) reviews Daily Sanitation Sheet

(In part, the definition of sanitize means to treat clean surfaces to kill microorganisms. In order for sanitizers to work effectively, the surface must first be cleaned. That cleaning process is listed as part of the sanitizing procedure in this example. While the example uses a quaternary ammonium sanitizer, other registered sanitizing chemicals, dry products, recognized hot water, or steam sanitizing procedures may be used.)

Preventive Control #2 requires sanitizing of animal food contact surfaces. The sanitizing procedure for finished product (post-extrusion) animal food contact surfaces in the ABC Pet Food Manufacturing Facility appears above. This is an example of how a sanitation control may be applied. The format used can vary considerably.

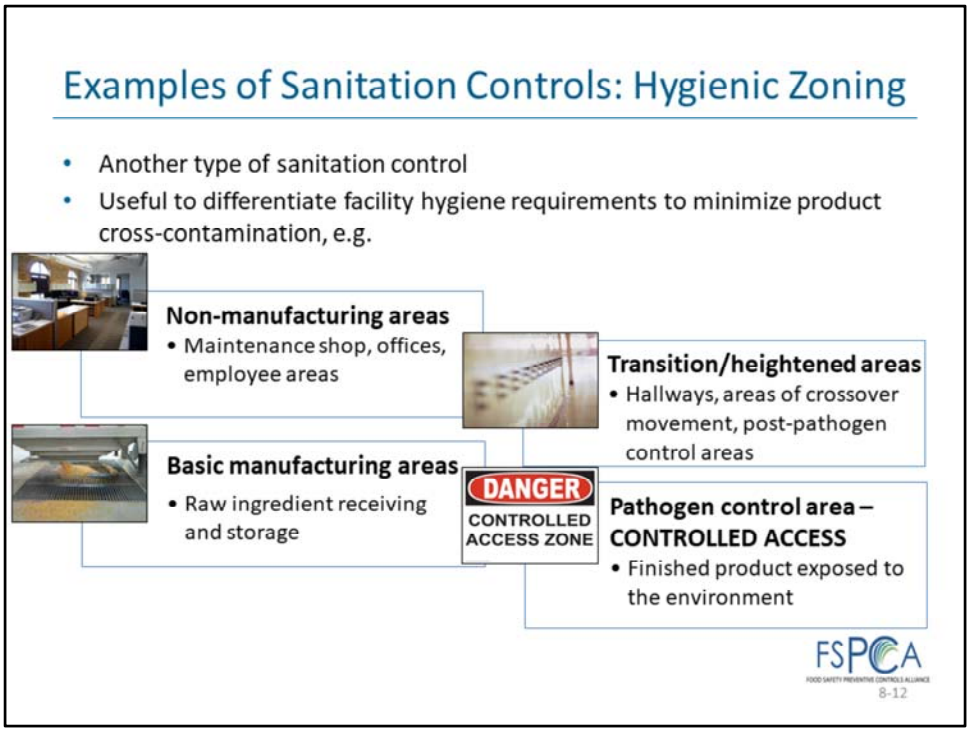
The purpose of this procedure is to clean and sanitize finished product animal food contact surfaces (equipment and utensils), because it is important for reducing cross-contamination or recontamination with environmental pathogens that may impact animal food safety.

The procedure is to occur prior to operations beginning and at the end of daily production by a sanitation team member.

In the procedure, the first step will be clean post-extrusion surfaces by removing

gross material, wiping the surfaces clean with an appropriate cleaning solution, and rinsing with clean water. Following the cleaning, a sanitizing solution (200 ppm quaternary ammonium compound solution) is sprayed on surface, which is then dried.

The SOP shows the monitoring, correction, corrective action, documentation, and verification activities that are expected to accompany this sanitation control. This facility has identified that the supervisor must complete daily verification that the preventive control is completed. However, the PCQI reviews those records on a weekly basis. The daily review is an optional activity being conducted by the facility. Verification of review is only required within 7 working days of the activity, and must be under the direction of the PCQI.



Sanitizing animal food contact surfaces is not the only control useful in preventing contamination of animal foods. Another potential type of sanitation control is hygienic zoning. The concept of hygienic zoning was developed for facilities where both raw materials potentially contaminated with undesirable microorganisms and finished products are handled. Every facility has different needs, depending on the product, the structure, traffic patterns and other factors involved with processing and handling animal food.

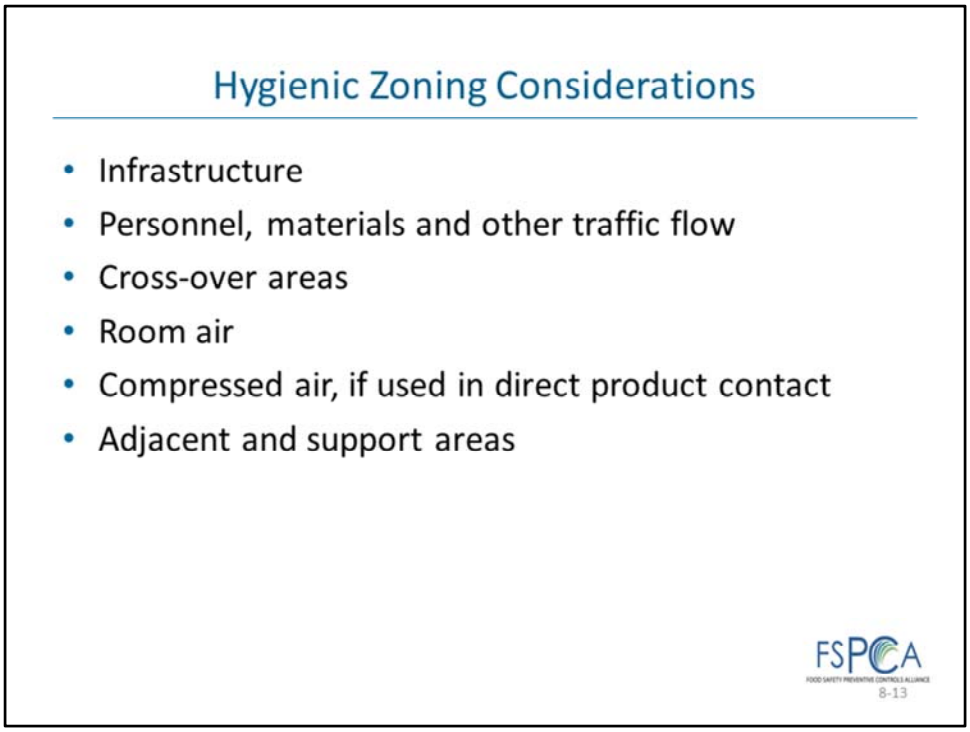
The slide above discusses different types of hygiene areas. Non-manufacturing areas do not require the same level of sanitation as animal food processing areas. Transition areas into a processing space or those in post-pathogen controls areas should be equipped with materials to minimize the potential for transferring potential pathogens into the facility. For example, hand-washing and footbath areas are typically available in transition areas. More attention to sanitizing and primary pathogen control is needed in areas that handle finished product that are exposed to the environment.

Control of traffic patterns between these areas with different levels of hygiene can minimize the transfer of hazards. Techniques that may be useful include:

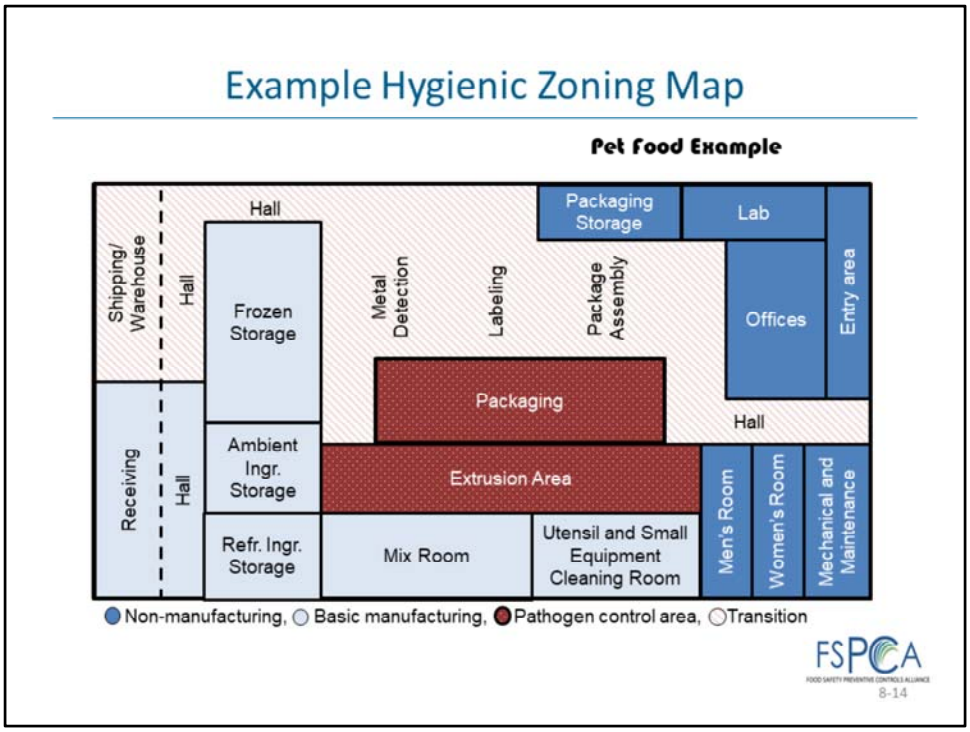
- Dedicated equipment in different areas, especially when it is difficult to clean (e.g., carts, forklifts)
- Use of color-coded uniforms or bump caps for people who work on the raw

material side and those who work on the finished product side
- Linear flow through a facility, such that raw material does not enter the finished product area.

It is understood that the above may not be practical in all situations. However, there is a requirement that efforts are made to prevent cross-contamination when *hazards requiring a preventive control* are identified through hazard analysis. Preventive controls can address this through zoning and other means, as dictated by the situation at the facility.



Each facility must determine the need for and scope of a sanitation control based on the potential for product contamination. The assessment should take into account the physical structure of the facility; personnel, packaging and ingredient traffic flows; and any cross-over areas. The assessment should also consider potential contaminants from raw materials, air flow, support areas and activities taking place in the facility, which may include potential microbiological concerns. The sanitation controls must address targeted environmental pathogens if relevant to the product being produced.



The map above is a hygienic zoning example for ABC Pet Food Manufacturing Facility. There are four main areas of this map: 1) non-manufacturing, 2) basic manufacturing, 3) pathogen control, and 4) transition areas.

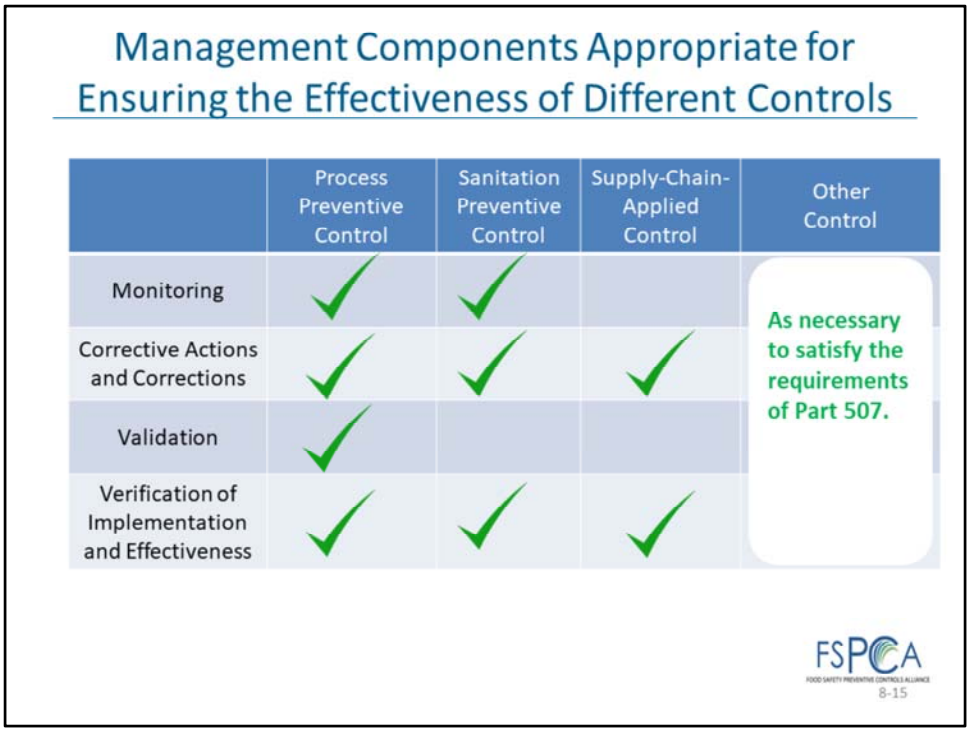
1) The non-manufacturing areas, depicted in dark blue shaded boxes, are areas where manufacturing does not occur, such as personnel entrances, laboratories, packaging storage, offices, maintenance and mechanical rooms, and restrooms. There should not be undesirable microorganisms in these areas.

2) The basic manufacturing areas, depicted in light blue shaded boxes, are areas where manufacturing occurs prior to the process control step (extrusion). These areas include material receiving, hallways, ingredient storage, mixing, and utensil cleaning rooms. The presence of undesirable microorganisms may occur in these areas because of their exposure to contaminated raw material. This is acceptable because the facility has a process control for the hazard, but these areas should be maintained so as to not grow or proliferate the undesirable microorganism.

3) The pathogen-control area, depicted in the red box with white polka dots, is the highest risk location for cross-contamination. This is where finished, extruded, pathogen-free product is exposed to the environment prior to packaging. This is the most tightly controlled area to limit the potential for cross-contamination.

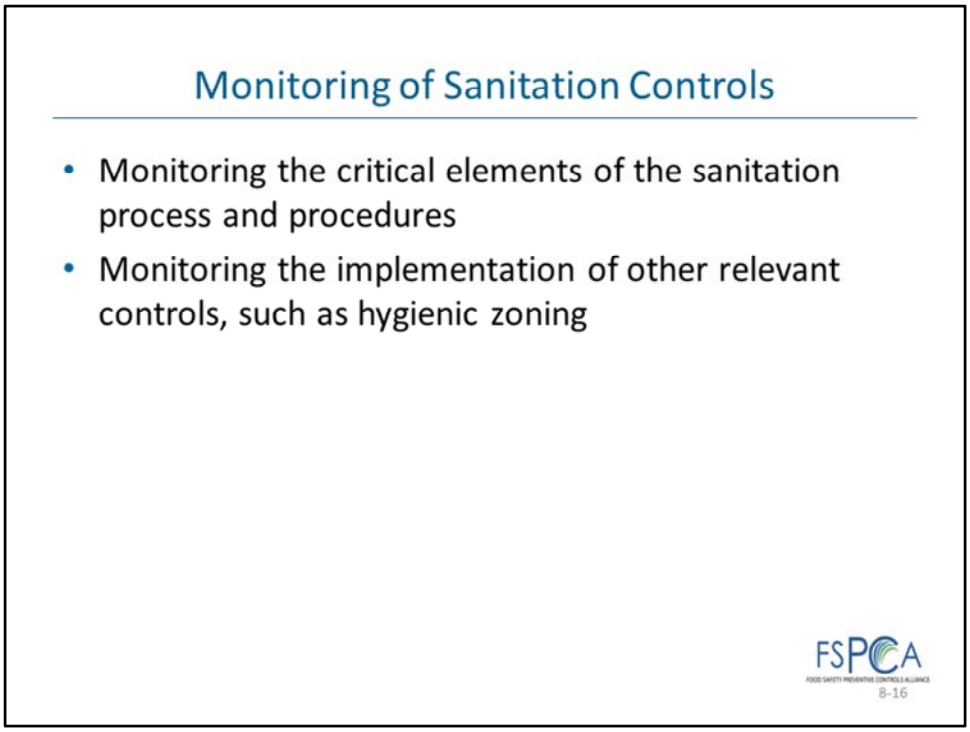
4) Areas after packaging are transition areas, depicted in the striped areas, include hallways, packaging assembly, labeling, metal detection, and shipping/warehouse. While finished product is not exposed in these locations, it is important to maintain a pathogen-free environment.

Employee zoning takes into account these zones and develops protocols for restricting employee movement from one zone to another, or describes requirements for what must occur prior to entry if these zones must be crossed. For example, employees in the packaging area should have limited contact with those receiving raw materials. There should be clear procedures for employees that cross over multiple areas, such as maintenance staff. If a member of maintenance works in a refrigerated storage area, returns to his workbench in the maintenance shop, and then must enter the packaging area, procedures should be established to ensure the employee does not contaminate his shop or the packaging area with undesirable microorganisms.



(Sanitation controls do not require validation because the control either cannot be validated, in the case of visual inspection, or is typically conducted by someone else, such as the sanitizer manufacturer to ensure its effectiveness. It is appropriate to ensure that the correct sanitizer is selected for the type of surface, animal food, and pathogen being targeted.)

The management components required for sanitation controls include monitoring, corrective actions and corrections, and verification activities. Note that validation is not a requirement for sanitation controls. These management components will be discussed next.



Sanitation controls must be monitored and results recorded as appropriate. As discussed above, sanitizing procedures used as a preventive control require monitoring records. An example of the type of record that could be used for monitoring the sanitizing activity is illustrated next.

Pet Food Example

Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

DATE: 4/18/2016 **Daily Sanitation Sheet**

Procedure	Prior to Operations (5:47 AM)	End (6:36 PM)	Comments or Corrections	Initials
Cleaning Animal Food-Contact Surfaces • Surface of equipment or utensil cleaned w/ squeegee	✓	✓	n/a	CS
• Surface wiped with clean cloth dipped in detergent Detergent type and strength: ABC Cleaning Solution, 2 oz. per gallon water	✓	✓	n/a	CS
• Surface rinsed with clean water	✓	✓	n/a	CS
Sanitizing of Animal Food-Contact Surfaces • Entire surface sprayed with sanitizer Sanitizer type and strength: Quaternary ammonium compound, 200 ppm	✓	✓	n/a	CS
• Allow at least 1 minute contact time of sanitizer	✓	✓	n/a	CS
• Allow surface to air dry (apx. 5 minutes)	✓	✓	n/a	CS
• ***Inspected for residual material and cleanliness	✓	✓	n/a	CS
• ***Sanitizer concentration measured: 200 ppm	✓	✓	n/a	CS

Supervisor signature: Susie Supervisor Date: 4/18/2016
Verification of reviewer signature: Frank F. Leader Date: 4/22/2016

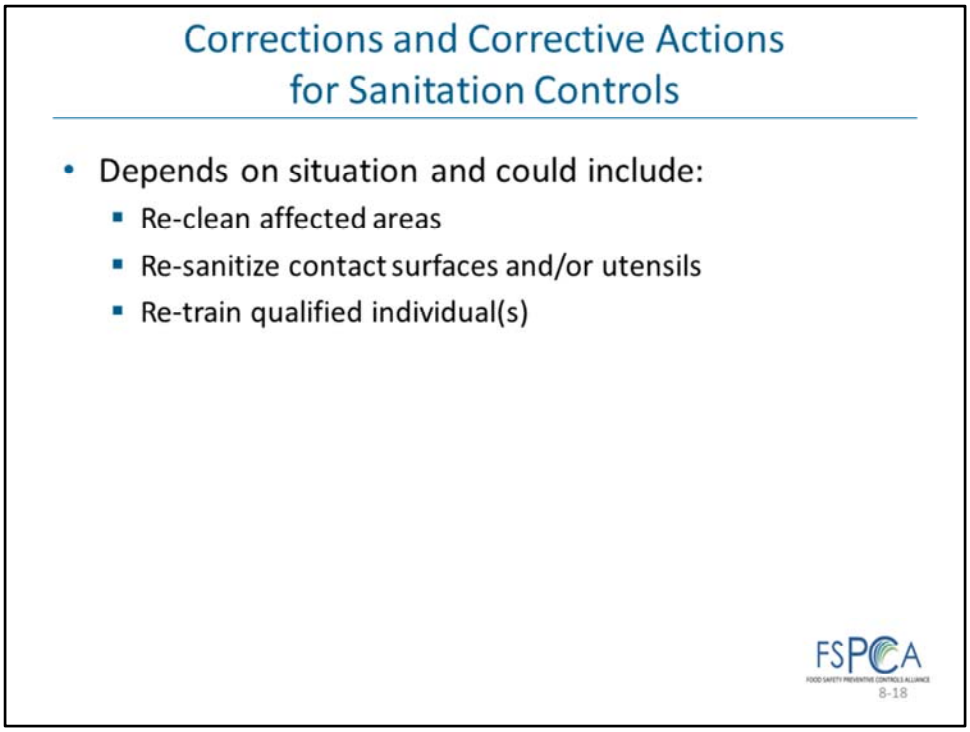
(This facility chose to use a two-step verification method. First, the supervisor reviews the monitoring record daily. Second, the PCQI reviews the record within 7 working days of the activity occurring. Only the second activity is a requirement.)

An example of a Daily Sanitation Sheet for dry extruded dog and cat food is illustrated above. The example is from our ABC Pet Food Manufacturing Facility. This form serves as documentation of the monitoring and verification steps for Preventive Control #2 according to the facility's SOP for finished product animal food contact surface sanitizing (see slide 8-11).

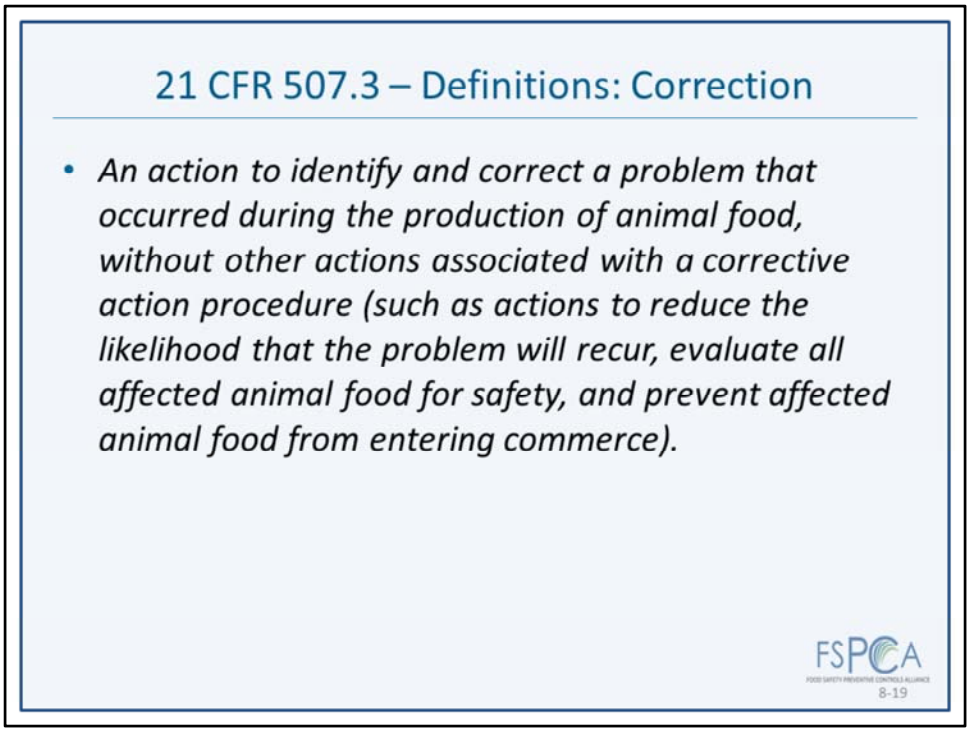
The concentration of the cleaning solution was recorded (ABC Cleaning Solution, 2 oz. per gallon water). The sanitizer concentration is tested using a sanitizer strip, and the concentration is recorded (quaternary ammonia compound, 200 ppm). The frequency of testing is recorded (prior to start and at the end of operations), as well. In this example, the monitoring activities are the inspection for residual material and cleanliness and the measurement of the sanitizer concentration. The type of monitoring activity and its frequency can change depending upon the facility, but both must occur. A chemical supplier can help provide guidelines for monitoring methods and frequency in many situations.
In addition to the sanitizer concentration and frequency, other key parts of this form include the date, time, and initials of the individual performing the monitoring task. These must be included on a monitoring record and must be recorded each time they

perform the task.

The last component of this form is the designated space for verification. In the facility's SOP for sanitizing post-extruder animal food contact surfaces (see slide 11), the supervisor is required to review and sign the Daily Sanitation Sheet, and the PCQI must verify it within 7-working days. Space is provided for their signatures and dates of those signatures.



When deficiencies of a sanitation preventive control are encountered, corrective actions or corrections must be made in a timely manner. The nature of the action depends on the specific situation. In some situations, corrections may be more appropriate than corrective actions. Sometimes corrections are relatively easy and can be done when animal food safety is not impacted. For example, if the sanitizer concentration from the previous example is determined to be incorrect, a new sanitizer solution should be prepared and the equipment should be re-sanitized. Note that re-sanitizing equipment can be avoided if the sanitizer concentration is checked before it is used. The facility may also determine that personnel cleaning the equipment may need to be retrained to ensure proper preparation of sanitizer solutions in the future.



Note that the discussion in the previous slide focused on a correction, not a corrective action. The term correction is defined by the *Preventive Controls for Animal Food r*ule as 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).

Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Pet Food Example

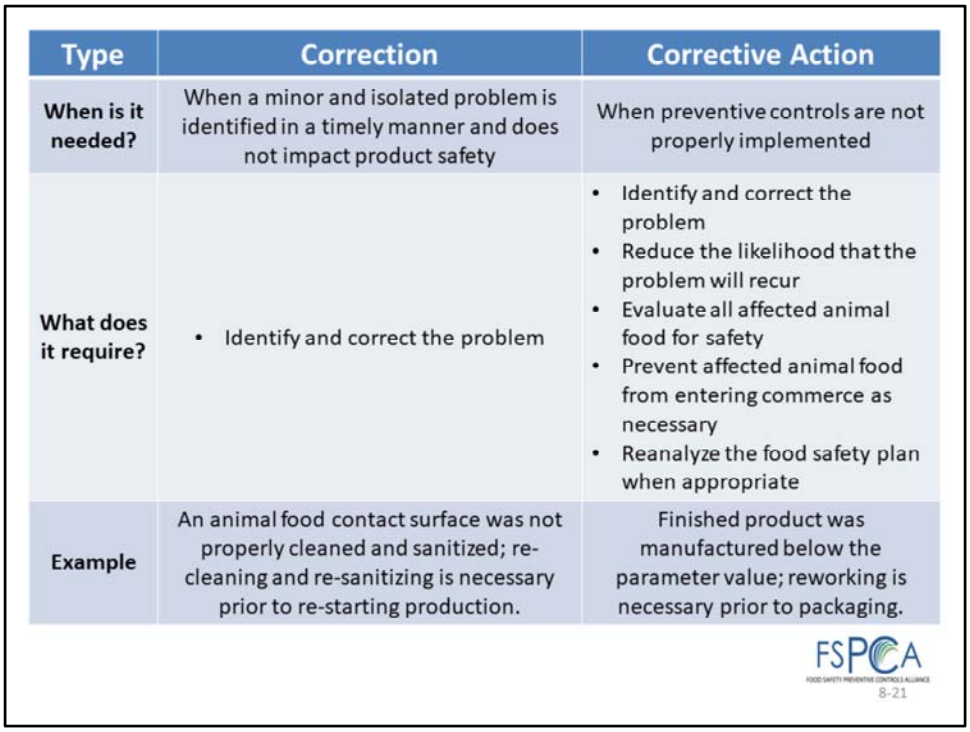
SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.
Frequency: Before operations begin and at the end of daily production
Who: Sanitation team member
Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet
Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.
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: Daily Sanitation Sheet
Verification: Supervisor (daily) and PCQI (within 7 working days) reviews Daily Sanitation Sheet

The example above from the ABC Pet Food Manufacturing illustrates how corrections can be described in a sanitizing procedure. This correction procedure informs operators the action that must be taken if procedures are not properly followed. Because these are correction procedures and not corrective action procedures, completion of a corrective action report is not required.



(Typically, corrective actions are necessary for process controls. Corrections are more likely to occur in sanitation controls. However, if repeated corrections are necessary, corrective action may be appropriate.)

Actions to correct conditions or practices related to cleanliness and prevention of cross-contamination must be taken in a timely manner. When timely action is taken, “corrections” such as those described in the sanitizing procedure, may be adequate. If action is not taken in a timely manner (e.g., unsanitary conditions exist for an extended period and result in product cross-contamination), a full corrective action may be required.

The slide describes the differences between corrective action and correction. A corrective action is needed when preventive controls are not properly implemented. When that occurs, the facility must 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, and reanalyze the food safety plan when appropriate. An example of a situation that would require a corrective action is if finished product was extruded at a temperature below the set parameter value. In that case, reworking the product would be necessary prior to packaging.

Comparatively, a correction is when a minor and isolated problem is identified in a

timely manner and that problem does not impact product safety. In this case, no additional steps are required beyond identifying and correcting the problem. An example of a correction is if residue is found on an animal food contact surface prior to production, which would require re-cleaning and re-sanitizing.

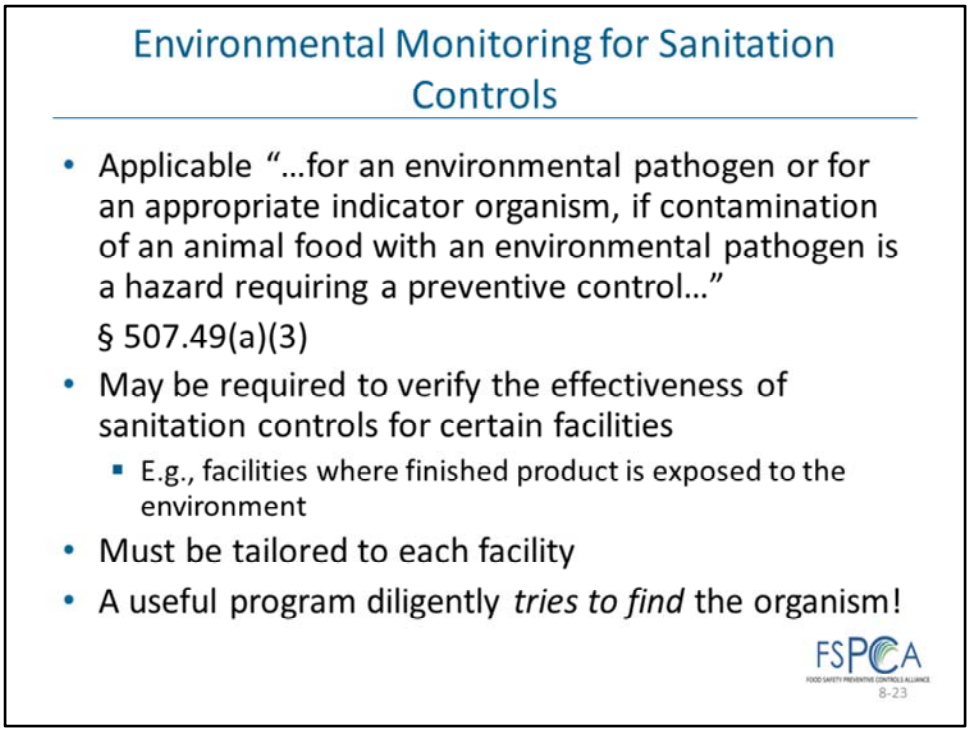
All corrective actions and corrections must be documented and are subject to verification to make sure that appropriate decisions were made and record review.

(Some facilities may monitor the hazard they are trying to control directly. However, there may be constraints for directly measuring some undesirable microorganisms, such as potential variability, cost, or speed with which they can be analyzed. For this reason, facilities may choose to use indicator organisms, which behave similarly to the hazard, but nonpathogenic and more appropriate to monitor.

Examples of indicators include *Enterobacteriaceae* or ATP swabs. *Enterobacteriaceae* is an indicator organism that behaves similarly as *Salmonella* spp. Swabbing for ATP indicates cleanliness of surfaces.)

Verification activities that may be appropriate for sanitation controls include confirming that the procedures, such as hygienic zoning or surface sanitization, are working as intended. The methods used to verify these activities vary based on the type of sanitation control, facility, and animal food manufactured processed, packed, or held.

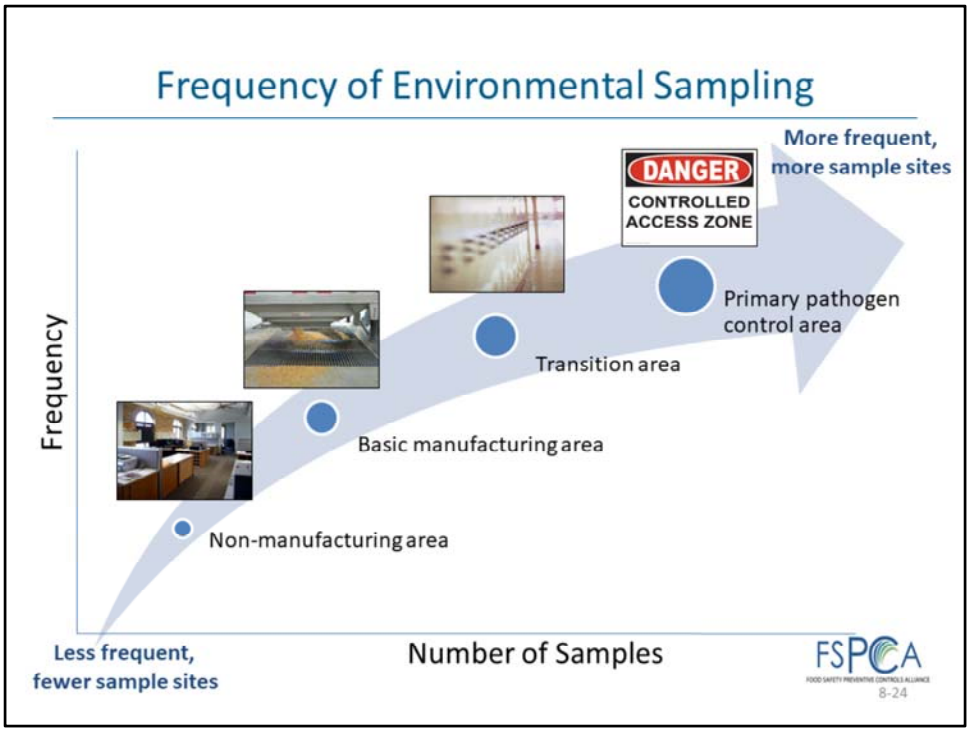
Verification activities may include reviewing records, such as Daily Sanitation Sheets. However, they may also include environmental monitoring of undesirable microorganisms or indicator organisms to ensure hazards are properly controlled.



(Environmental monitoring is specifically described as being appropriate for *Salmonella* spp. and *Listeria monocytogenes* (21 CFR 507.3).)

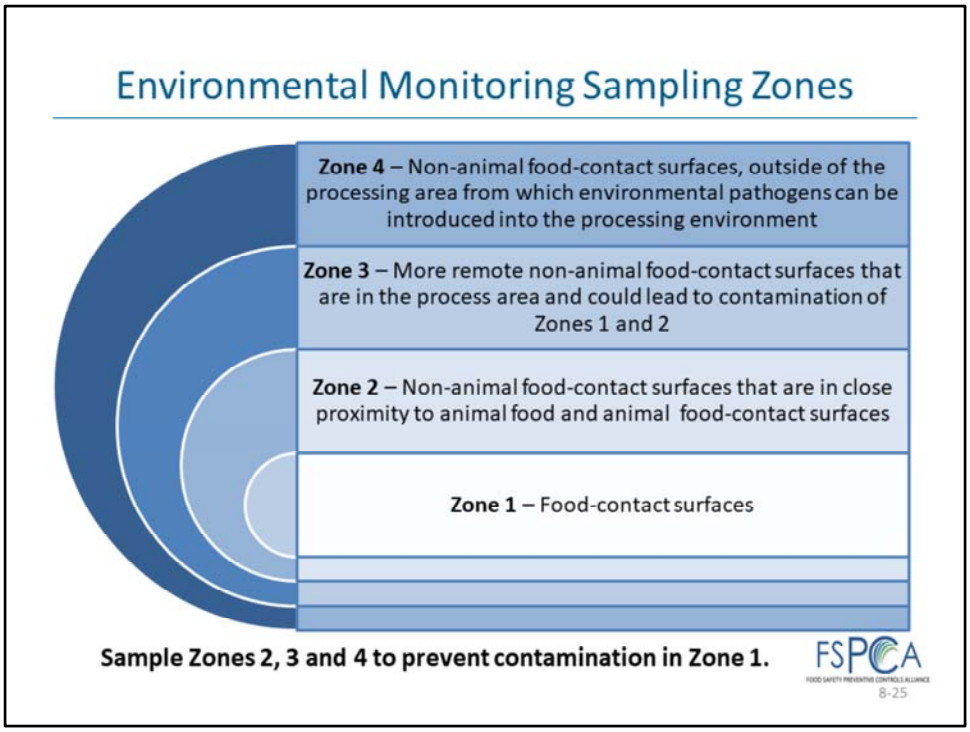
Environmental monitoring is usually applicable for a pathogen or an appropriate indicator organism when an environmental pathogen is a *hazard requiring a preventive control*. In this case, environmental monitoring helps verify the effectiveness of sanitation controls for certain facilities. For example, this would be common in facilities where finished product subject to biological hazards is exposed to the environment before packaging.

An effective environmental monitoring program diligently tries to find the pathogen or indicator organism of concern so that corrections can be made *before* product is compromised. Environmental monitoring is a verification procedure for such a facility. Corrective actions procedures (instead of corrections) must document actions to be taken when the environmental pathogen or an indicator organism is detected.



There are two major considerations when determining procedures for environmental monitoring. First, one must consider where in the facility layout to focus swabbing activities. Second, one must consider which surfaces to swab within each of those areas.

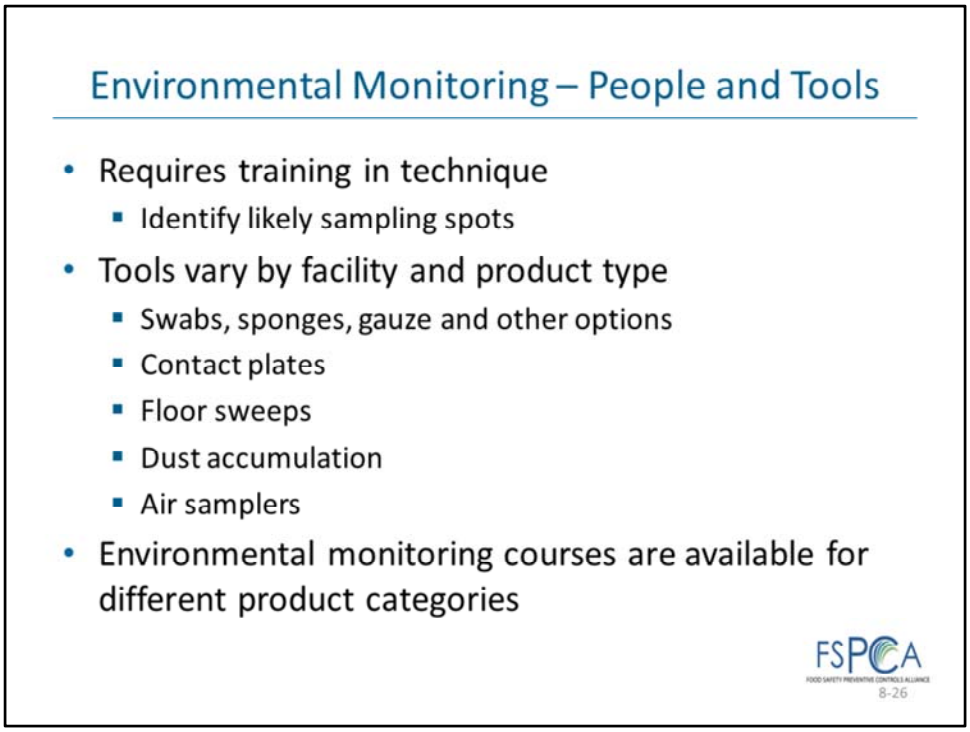
Since the objective of environmental monitoring is to detect potential sources of contamination, sampling typically focuses on the areas of greatest concern. There are less frequent and fewer sample sites in non-manufacturing areas, such as office areas. The frequency and number of sampling sites increases based on risk area, where the most frequent and largest number of sampling sites are in the primary pathogen control area, such as in the packaging area described previously where finished product is exposed to the environment.



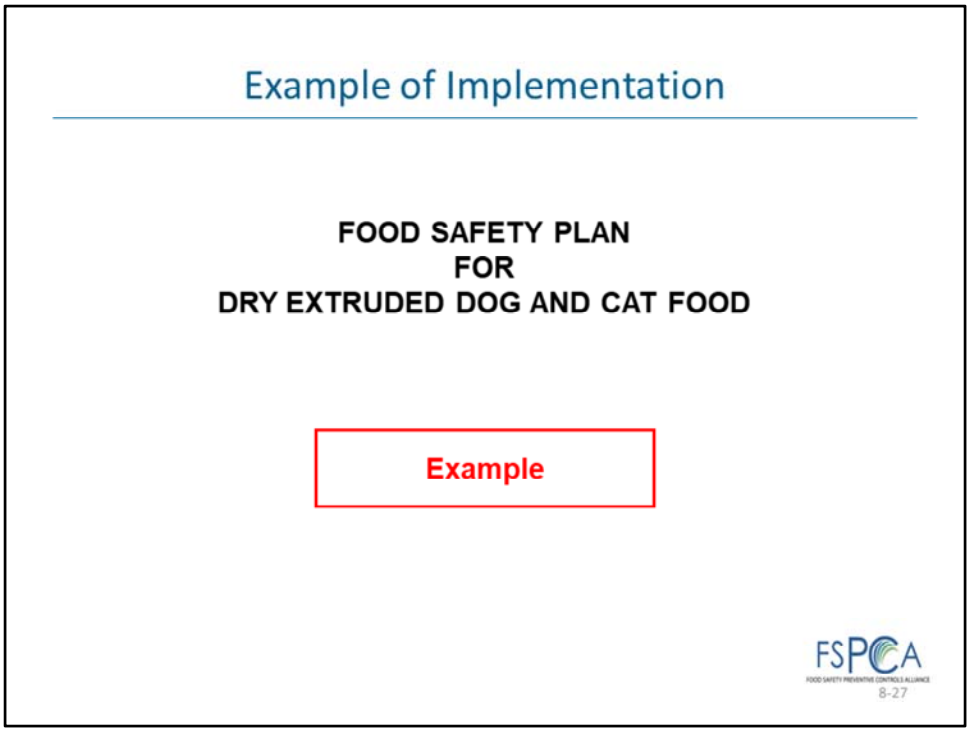
Once the frequency and number of sampling sites is determined within each processing area, the specific sampling sites within each area are typically determined based on zones. Zoning again helps prioritize the locations and appropriate frequency of swabbing for environmental monitoring.

Zone 1 represents animal food contact surfaces, such as the interior of bins, conveyors, utensils and equipment that come into direct contact with the animal food.
Zone 2 includes areas adjacent to animal food contact surfaces, which are sometimes referred to as indirect product contact surfaces. Examples include bearings and the exterior of equipment panels.
Zone 3 includes other surfaces within the area, such as floors, walls, ceilings, and drains.
Zone 4 encompasses all other non-production areas of a facility, such as hallways, maintenance shops, and restrooms.

Sampling of Zone 1 is often difficult because it is covered during the process. Thus, sampling Zone 1 is infrequent; but when it is done, product should be held until results are found negative to prevent a potential recall. Instead, most facilities focus on sampling Zones 2 and 3 in order to detect potential contamination *before* it is found in product so it can be corrected.



Personnel must be trained to conduct environmental sampling and must have a sense for when to deviate from the plan based on observations or special events. The correct tools allow for thorough sampling of various locations, such as cracks, crevices, air, large floor areas, and drains. Because there are a number of variables to consider in order to conduct accurate and effective environmental monitoring, additional training may be appropriate.



The following slides provide an example of how a sanitation control may be utilized in a food safety plan. We will return to the Example Food Safety Plan for Dry Extruded Dog and Cat Food that was introduced in Chapter 5, and also discussed in Chapter 7. Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	B	*Salmonella* spp.

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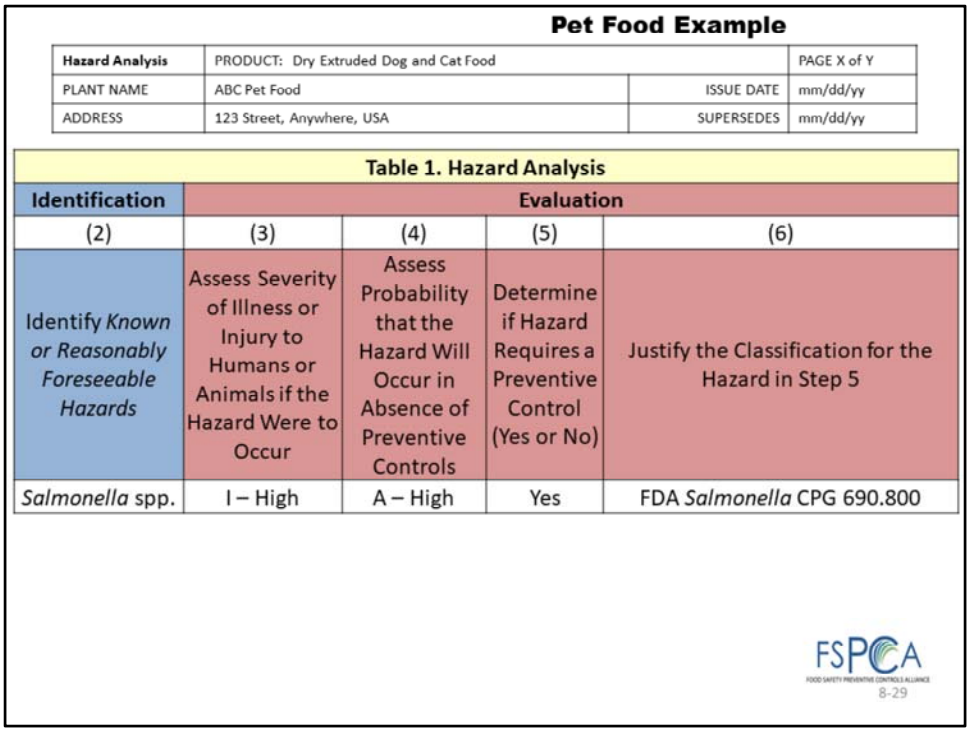
8-28

In this example plan, *Salmonella* has been identified as a known or reasonably foreseeable biological hazard. Ingredients were identified as its potential vector of entry.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify *Known or Reasonably Foreseeable Hazards*	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	I – High	A – High	Yes	FDA *Salmonella* CPG 690.800

FSPCA

8-29

In Chapter 5, the determination of severity and probability was discussed. Because *Salmonella* can potentially cause illness in both animals and humans, and because pet foods are direct human contact foods with a zero tolerance level for the pathogen according to the FDA Compliance Policy Guide, it was determined that the hazard requires a preventive control.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Salmonella spp.	Sanitation Control - Post-extruder surface sanitizing	2

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8-30

Chapter 7 described how extrusion temperature could be used as a process control to reduce *Salmonella*. However, extrusion is a point-in-time mitigation step and does not prevent potential cross-contamination with the hazard after thermal processing. Thus, sanitizing post-extruder animal food contact surfaces was determined necessary to prevent cross-contamination. This is Preventive Control Number 2 in the Example Food Safety Plan for Dry Extruded Dog and Cat Food (Preventive Control Number 1 was extrusion temperature).

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

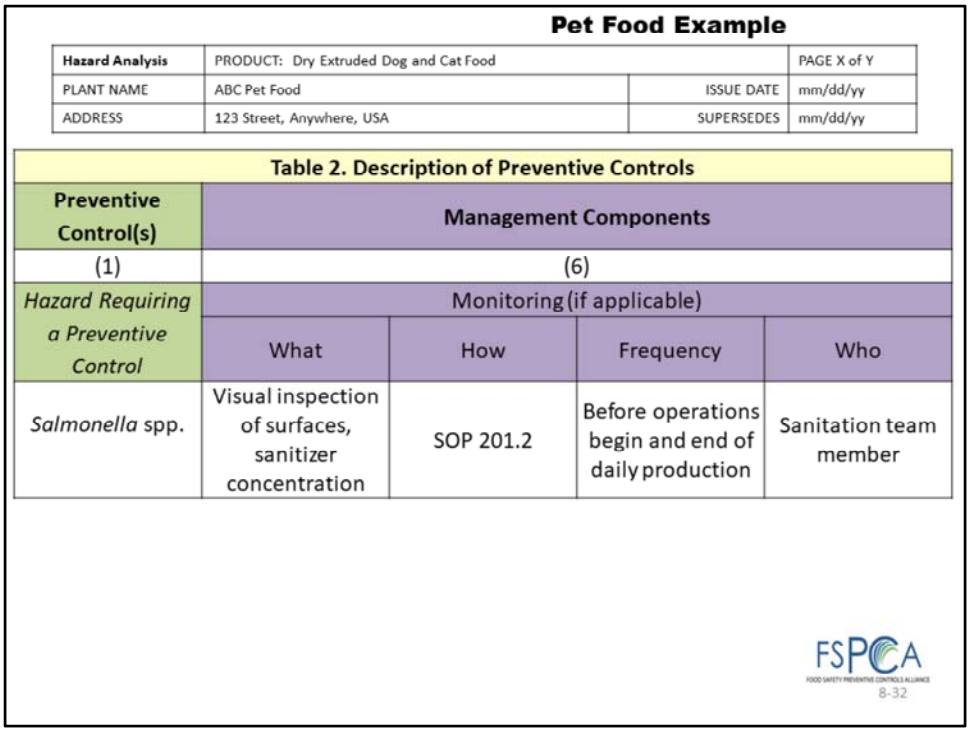
Table 2. Description of Preventive Controls

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)
Salmonella spp.	Post-extruder surface sanitizing	2	Sanitation Control	Any residual material on post-extruder surfaces or 200 ppm sanitizer concentration

FSPCA

8-31

Table 2 of the food safety plan describes the preventive controls and any applicable management components. As established by the previous procedure, there are two parameters: 1) any residual material on post-extrusion animal food contact surfaces; and 2) 200 ppm concentration of the quaternary ammonium compound solution.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

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
Salmonella spp.	Visual inspection of surfaces, sanitizer concentration	SOP 201.2	Before operations begin and end of daily production	Sanitation team member

FSPCA

8-32

The monitoring for this preventive control is visual inspection of the animal food contact surfaces for gross contamination and using a test strip to test the quaternary ammonium compound solution before its application to clean animal food contact surfaces. The procedures for how to conduct this monitoring are discussed in a company standard operating procedure – SOP 201.2. The monitoring will occur before operations begin and at the end of daily production by a sanitation team member.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

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
Salmonella spp.	Correction: If residual material is observed on the animal food-contact surface, re-clean and re-sanitize. If sanitizer is not at the proper concentration, make a new solution. 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	Daily Sanitation Sheet, corrective action and correction records, training records, environmental monitoring records

If there is residual material on the animal food-contact surface, the surface is to be re-cleaned and sanitized as part of a correction. If the quaternary ammonium solution is not at the proper concentration, a new solution will be made. Both those instances are corrections.

If unsanitary conditions exist for an extended period and result in product cross-contamination or repeated corrections are necessary, corrective action is necessary, where the problem must be identified and corrected, and product must be reworked prior to packaging.

The records required for these activities include the Daily Sanitation Sheet, corrective action and correction records, training records, and environmental swabbing records.

Pet 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	Environmental monitoring per SOP 213.6 Product testing when necessary per SOP 213.7
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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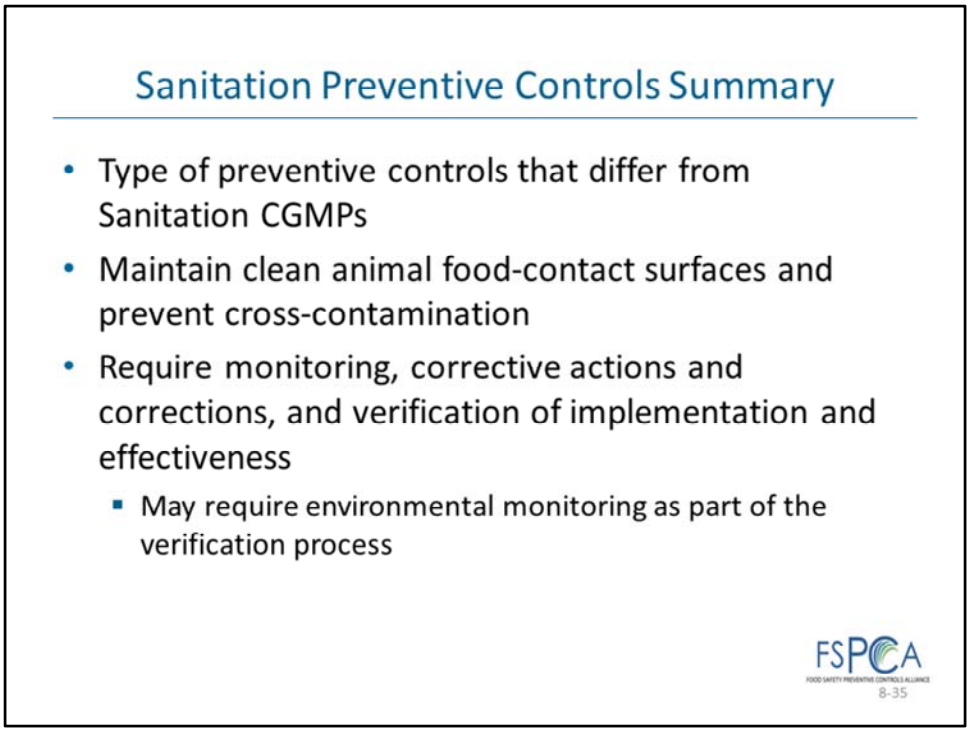
7-40

Verification activities include record review, environmental monitoring, and reanalysis.

The daily sanitation sheet will be reviewed within 7 working days of the documented action unless justified by the PCQI. Environmental monitoring will be conducted according to internal procedures outlined by SOP 213.6, while product testing will be conducted according to procedures in SOP 213.7. Other monitoring records, as well as corrective action and correction records will be reviewed within seven working days. If the review timeframe must exceed seven working days, a written justification is provided by the PCQI.

There is no validation required for a sanitation control.

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



In summary, it is important to understand that sanitation controls are a type of preventive control and that use of this type of preventive control differs from Sanitation CGMPs. The intent of sanitation controls is to maintain clean animal food contact surfaces and prevent cross-contamination of undesirable microorganisms into finished animal food. Sanitation controls require monitoring, corrective actions and corrections, and verification of implementation and effectiveness. Typically, correction is utilized more frequently than a corrective action for sanitation controls, and environmental monitoring may be an appropriate verification activity.

This concludes the focus on sanitation controls. The next chapter will describe the final type of preventive control, a supply-chain-applied control.

Exercise 8

- A facility has determined *Salmonella* spp. is a *hazard requiring a preventive control*. Is the following scenario a Sanitation CGMP or Sanitation Control?
  1. Employees wash their hands and don gloves prior to handling finished product to collect a sample.
  2. Floors and walls in the refrigerated ingredient storage area are cleaned and sanitized.
  3. The interior of the finished product surge conveyor is cleaned and sanitized prior to beginning packaging.
  4. Swabs are collected from the floor between the extrusion, packaging, and warehouse area and analyzed for undesirable microorganisms.
  5. Surfaces are dried after wet cleaning.
- When is dry vs. wet cleaning appropriate?
- When is employee zoning appropriate? How would you apply it?

Exercise 8 Summary

- Sanitation controls are different from sanitation CGMPs.
  - Used mainly to prevent cross-contamination of biological *hazards requiring a preventive control*.
- It is impractical for many facilities to use wet cleaning. Whenever it is used, the water or sanitizer cannot be a source of potential contamination itself.
- Hygienic zoning may be successfully used to prevent cross-contamination from employees, but it can be complicated to develop and implement.