FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

ANIMAL FOOD EXERCISE WORKBOOK

This workbook was created to assist participants in the Food Safety Preventive Controls Alliance's *Preventive Controls for Animal Food* course to practice exercises in an attempt to reinforce learning.

All exercises and examples are hypothetical. Application of preventive controls requires in-depth knowledge of actual operating conditions, thus information in the curriculum and in exercises may not be directly applicable to a specific operation. Assistance from a preventive controls qualified individual may be necessary to ensure compliance with FDA regulations.

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Chapter 1: Introduction to Course and Regulatory Overview

Background

A *Qualified Individual* (QI) is: "A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment."

A *Preventive Controls Qualified Individual* (PCQI) is: "A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system."

Reflection

1. How is a QI similar or dissimilar to a PCQI?

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2. How do you anticipate training *Qualified Individuals* for: 1) completing their duties in a way that results in safe food; 2) animal food hygiene and animal food safety, including the importance of employee health and personnel hygiene? How will you document that training?

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3. As a PCQI, which tasks from the list on Slide 1-21 do you: 1) feel comfortable performing; 2) hope to learn; and 3) plan to use outside resources to complete?

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4. 'Management' is responsible for compliance with Subpart B: Current Good Manufacturing Practice. Who in your facility (or a facility you have visited/inspected) is it when the rule references 'management'?

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5. The 'owner, operator, or agent-in-charge' of the facility is responsible for compliance with Subpart C: Hazard Analysis and Risk-Based Preventive Controls outlined in the Food Safety Plan. Who in your facility (or a facility you have visited/inspected) is it when the rule references 'owner, operator, or agent-in-charge'?

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Chapter 2: Current Good Manufacturing Practice

Background

The Current Good Manufacturing Practices are considered by FDA to be: "…necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

The CGMPs establish baseline standard for the production of safe animal food and the creation of a successful Food Safety Plan.

Reflection

1. Which CGMP requirements do you consider already successfully implemented within your facility (or a facility you have visited/inspected)?

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2. Which CGMP requirements do you anticipate will be the most challenging to implement within your facility (or a facility you have visited/inspected)?

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3. Describe at least one scenario where the same situation may be either acceptable or a violation of a CGMP requirement depending upon different factors, such as the type of animal food, production process, manufacturing environment, and facility design.

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Chapter 3: Animal Food Safety Hazards

Background

Hazard means: "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals."

Known or Reasonably Foreseeable Hazard means: "a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food."

Hazard Requiring a Preventive Control means: "A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system."

Reflection

Consider a single type of animal food manufactured within your facility or a facility you have visited or inspected.

1. What are the ingredients or raw materials used in that animal food?

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2. What are the process steps used for the manufacturing, processing, packing, or holding of that animal food?

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3. What are the *Known or Reasonably Foreseeable Hazards* associated with the ingredients and facility?

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4. Are there are any *Hazards Requiring a Preventive Control*? If yes, list them.

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5. Are there common preventive controls used to significantly minimize or prevent the hazard for that type of animal food?

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Chapter 4: Overview of the Food Safety Plan

Background

A written food safety plan must include a hazard analysis and implementation records, such as training documentation for *Qualified Individuals* and the PCQI as applicable. If the hazard analysis determines there is a *hazard requiring a preventive control*, the food safety plan must also identify preventive control(s) and management components and a recall plan.

The format of a food safety plan is flexible to meet the needs of a facility. However, it must be reanalyzed at least every 3 years or more frequently, as appropriate.

Reflection

Either alone or in small groups (2-3 individuals), determine for your own facility, a facility you have visited, or a facility you have inspected, each of the following:

1. Do you anticipate using any of the recommended components, such as a list of food safety team members, facility overview, or flow diagram? Why or why not?

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2. Does the facility currently have any of the required components of a food safety plan?

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- If yes, what elements are missing? How do you envision incorporating any missing components into a food safety plan (i.e. how do you envision organizing the plan and its required components?
- If no, what format do you anticipate using to organize the required components?

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3. How do you envision organizing records generated in support of the food safety plan activities?

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Table 1. Hazard Analysis

Identification			**Evaluation**				**Preventive Control(s)**	
(1)	(2)		(3)	(4)	(5)	(6)	(7)	(8)
List Ingredients and Steps/Equipment within the Process Flow	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	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
	B							
	C							
	P							
	B							
	C							
	P							

Chapter 5: Hazard Analysis and Preventive Controls Determination

Background

A written food safety plan must include a hazard analysis and implementation records, such as training documentation for *Qualified Individuals* and the PCQI as applicable. If the hazard analysis determines there is a *hazard requiring a preventive control*, the food safety plan must also identify preventive control(s) and management components and a recall plan.

The format of a food safety plan is flexible to meet the needs of a facility. However, it must be reanalyzed at least every 3 years or more frequently, as appropriate.

Reflection

1. Describe how the hazard analysis and preventive controls determination can change based on the type of animal food being manufactured or the facility in which is it is manufactured, processed, packed, or held.

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2. How would you consider formatting the justification for hazard analysis, particularly for the determination that there is not a *hazard requiring a preventive control*?

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Table 2. Description of Preventive Controls

Preventive Control(s)					**Management Components**					
(1)	(2)	(3)	(4)	(5)	(6)				(7)	(8)
Hazard Requiring a Preventive Control	Appropriate Control for *Hazard Requiring a Preventive Control*	Preventive Control Number	Preventive Control Category	Parameters (if applicable)	Monitoring (if applicable)				Corrective Action(s) and/or Correction(s)	Records
					What	How	Frequency	Who		

Chapter 6: Required Preventive Control Management Components

Background

Preventive Controls are: "Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."

Monitor means to: "To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended."

Written corrective action procedures must be established and implemented if preventive controls are not properly implemented.

Reflection

1. Describe how the monitoring and corrective action and/or correction procedures can change based on the type of animal food being manufactured or the facility in which is it is manufactured, processed, packed, or held.

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2. How would you consider managing the records generated to document the management components for a *hazard requiring a preventive control*?

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Table 3. Description of Verification Activities	
Activity	Description of Activity
Type of Validation (if applicable)	
Assurance that Monitoring and Corrective Actions or Corrections are Completed as Directed	
Type of Verification of Implementation and Effectiveness	
Reanalysis of food safety plan	

Chapter 7: Process Preventive Controls

Background

Verification means: "The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan." It is comprised of 1) validation, 2) verification that monitoring is being conducted as required, 3) verification that appropriate decisions are being made about corrective actions as required, 4) verification of implementation and effectiveness, and 5) reanalysis of the food safety plan.

Validation means: "Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."

Reflection

1. With new information about parameters presented in this chapter, would you change the parameter value selected in Exercise 6? How would you establish the parameter value?

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2. Is validation a required management component for the *Preventive Control* you selected? If so, how would you validate the preventive control? What resources would be necessary?

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3. Are there any other necessary activities for the verification of implementation and effectiveness? If so, what are they?

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4. When will monitoring and corrective action and/or correction records be reviewed?

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5. When is reanalysis of the food safety plan necessary?

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Chapter 8: Sanitation Preventive Controls

Background

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."

Sanitation preventive controls must include, as appropriate, cleanliness of animal food-contact surfaces and prevention of cross-contamination from objects and personnel to animal food and from raw to finished material.

Reflection

1. Describe differences between Sanitation CGMPs and sanitation controls.

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2. When is it appropriate to wet clean vs. dry clean? What would be the most appropriate for your facility (or a facility you have visited/inspected)?

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3. How can hygienic zoning be used to prevent cross-contamination from raw material, objects, and employees into finished product? How could it be implemented within a facility?

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Chapter 9: Supply-Chain-Applied Controls

Background

A *Supply-Chain-Applied Control* is: "A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt."

The supply-chain program must approve suppliers and determine, conduct, and document supply-chain verification activities, such as onsite audits, sampling and testing, review of a the supplier's relevant food safety records, and other activities based on risk. An onsite audit is a required verification activity for serious hazards unless otherwise justified. Good communication and documentation are key elements of successfully implementing supply-chain-applied controls.

Reflection

1. Describe how the supply-chain program outlined in the *Preventive Controls for Animal Food* rule is different than what the animal food industry typically considers as an approved supplier program.

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2. Consider an ingredient in your facility (or a facility you have visited/inspected). Who is the supplier of that ingredient according to the supply-chain program?

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3. Who must approve suppliers in a supply-chain-applied control? How could this activity be accomplished in your facility (or a facility you have visited/inspected)?

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4. If a facility substantially changes the physical or chemical characteristics of an animal food, such as by grinding, how might that change the supplier designation?

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Chapter 10: Recall Plan

Background

A recall plan is required if a facility has a *hazard requiring a preventive control*. The written recall plan must have assigned responsibility for completing procedures, a plan for notifying consignees and the public, a way to check effectiveness, and methods to dispose of recalled animal food.

Reflection

1. What are the required components of a recall plan?

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2. How might you measure the success of a recall plan?

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3. Describe some appropriate methods to dispose of recalled animal food.

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