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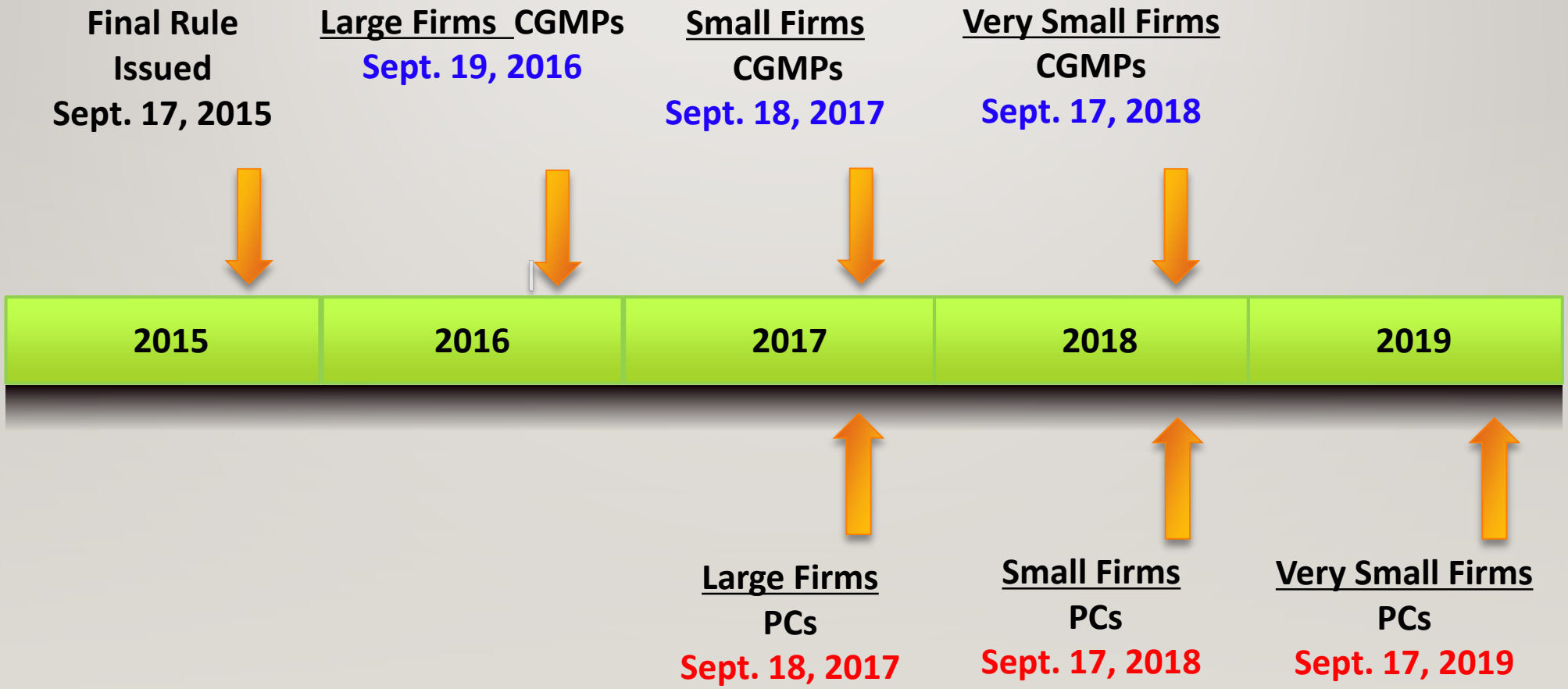
FOOD SAFETY MODERNIZATION ACT HAZARD ANALYSIS AND PREVENTATIVE CONTROLS

JANUARY 10TH

2018

CGMPs and Preventive Controls Animal Food Rule Compliance Dates



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What has changed for:

- Compliance Deadlines
- Inspection Start Dates
- The Latest FDA announcement on Enforcement discretion Relating to FSMA Provisions

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The Food Safety Plan

Hazard Analysis and Preventative Controls

What is a PCQI ?

A “preventive controls qualified individual” (**PCQI**) must develop (or oversee the development of)the FSP (Food Safety Plan).

A **PCQI** is a person with the education, training, or experience (or a combination of these) to develop and apply a food safety system.

A **PCQI** can be qualified through job experience or by completing training equivalent to the standardized curriculum recognized as

adequate by FDA (e.g., the Food Safety Preventive Controls Alliance (FSPCA) training). The

PCQI does not need to be an employee of the facility.

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Preventive control requirements mandate that animal food facilities identify and evaluate ***"known and reasonably foreseeable 'hazards'"*** associated with the facility and its animal food and implement one or more "***preventive controls"*** and components to manage such controls (monitoring, verification, corrections and corrective actions, records, and recall plans) for ***"hazards requiring a preventive control"***
A **written food safety plan** must be developed

Preventive controls means 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

Definitions

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

Definitions

- ***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 Definitions / Examples

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

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C = Chemical hazards, including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins', decomposition, and unapproved food or color additives

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P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

Hazard Definitions / Examples

- Biological hazards –

  Bovine Spongiform Encephalopathy (BSE) Caused by carryover in a transportation vehicle.

  Possible pathogens spread from farm to farm or farm to human through the use of reused bags.

  Salmonella in pet food ingredients

Hazard Definitions / Examples

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Hazard Definitions / Examples

Chemical hazards –

- Medication or nutrient carry over in mixers
- Incorrect labeling for medication
- Mix uniformity (over / under mixed)
- Incorrect formulation or nutrient levels.
- Copper or Urea carry over in mixers.

Hazard Definitions / Examples

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- Mold/Mycotoxins in incoming ingredients.
  Salt or Hydraulic fluid entering in the receiving pit from a delivery vehicle.
  Non food grade lubricants coming into contact with animal food.

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- Foreign material in incoming ingredients, (metal, tools, wood chunks, broken glass, plastic pieces).

Metal leftover from repairs to manufacturing or product handling equipment.

Unintentional adulteration of feed from items falling into mixers from floor access points that were not properly covered.

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Food Safety Plan

Write up brief Description of facility, types of animal food manufactured and what type of processes you use.

Not required but will help to tell your story

Here it is important to write up a brief description and history of your facility.
List what types and forms of feeds are produced here. How they are produced and what species of animals that you manufacture for.

Food Safety Plan

Brief History

ABC feed manufacturing company was started in 1932 and has a deep history of providing quality feed products to the surrounding area. This facility was primarily a grind and mix business and served mostly the hog and dairy industry. The business was sold to John and Tim Smith in the spring of 1980. The facility expanded to 2 locations and currently manufactures a variety of feed and mineral product for the livestock industry.

Food Safety Plan

Facility Overview

ABC company would fall In the FSMA Category of a small company. The Annual sales are over 2.5 Million and they employee 30 people. The facility manufactures supplements and complete feeds for Dairy, swine, poultry, and beef cattle

The facility operates Monday through Friday, excluding national holidays or days for scheduled maintenance. ABC company, currently operates 2 shifts of 6 people in the manufacturing area.

Food Safety Plan

Facility Overview

The facility manufactures medicated feeds, but it does not maintain a FDA medicated feed mill license. The facility does not use any Category II medications.

The facility utilizes bulk and bagged ingredients for manufacturing finished products. Bulk ingredients are either Received in through a receiving pit or are delivered pneumatically. A majority (80-90%) of finished products are sold as bulk.

Food Safety Plan

Facility Overview

ABC company employees 3 livestock nutritionist and an inhouse technical specialist.

The facility formulates and labels most of its own feeds.

The facility also manufactures for other feed manufacturing facilities and for customers that are served by independent nutritionists.

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Food Safety Plan

Facility Overview

The manufacturing area Utilizes 3 different mixers.

A 4 ton ribbon Mixer (most all bulk formulas are manufactured here).

A 2 ton Paddle mixer for mixing texturized feeds

A 1 ton paddle mixer for manufacturing mineral premixes.

The facility also operates a pellet mill for bulk and bagged finished products.

Food Safety Plan

The Animal Food Safety Team

- The animal food safety team is comprised of Five people:
  - ABC Company Owner
  - ABC Company Mill Manager
  - ABC Company Head Mixer
  - ABC Company Office Manager
  - ABC Company Logistic Manager

Food Safety Plan

The animal Food Safety Team

We are a small manufacturing company so the animal food safety team is comprised of management, employee’s have oversite of all manufacturing labeling and product quality areas.

Food Safety Plan

Product Description

ABC Company manufactures complete feeds, Protein Supplements texturized feeds and vitamin mineral supplements. These feeds are intended for swine, horses, goats, sheep, poultry, dairy and beef cattle. All products are manufactured using the same equipment. While using our prerequisite program to implement processes, Policies and training to ensure safe animal food product.

Food Safety Plan

Product Description

Master formula files are maintained for each product with labeling information developed to comply with AAFCO and State of Wisconsin requirements.

Food Safety Plan

Product Description

- Ingredients are blended per requirements of recipe and processes as defined in written procedures and processes.

- Finished products may be Bagged or Bulk and may be in pellet or granular form.

Food Safety Plan

Product Description

- All products are labeled in compliance with AAFCO and State of Wisconsin requirements.

- All bulk and bagged finished products are provided to customers within a 150-mile radius of the manufacturing facility.

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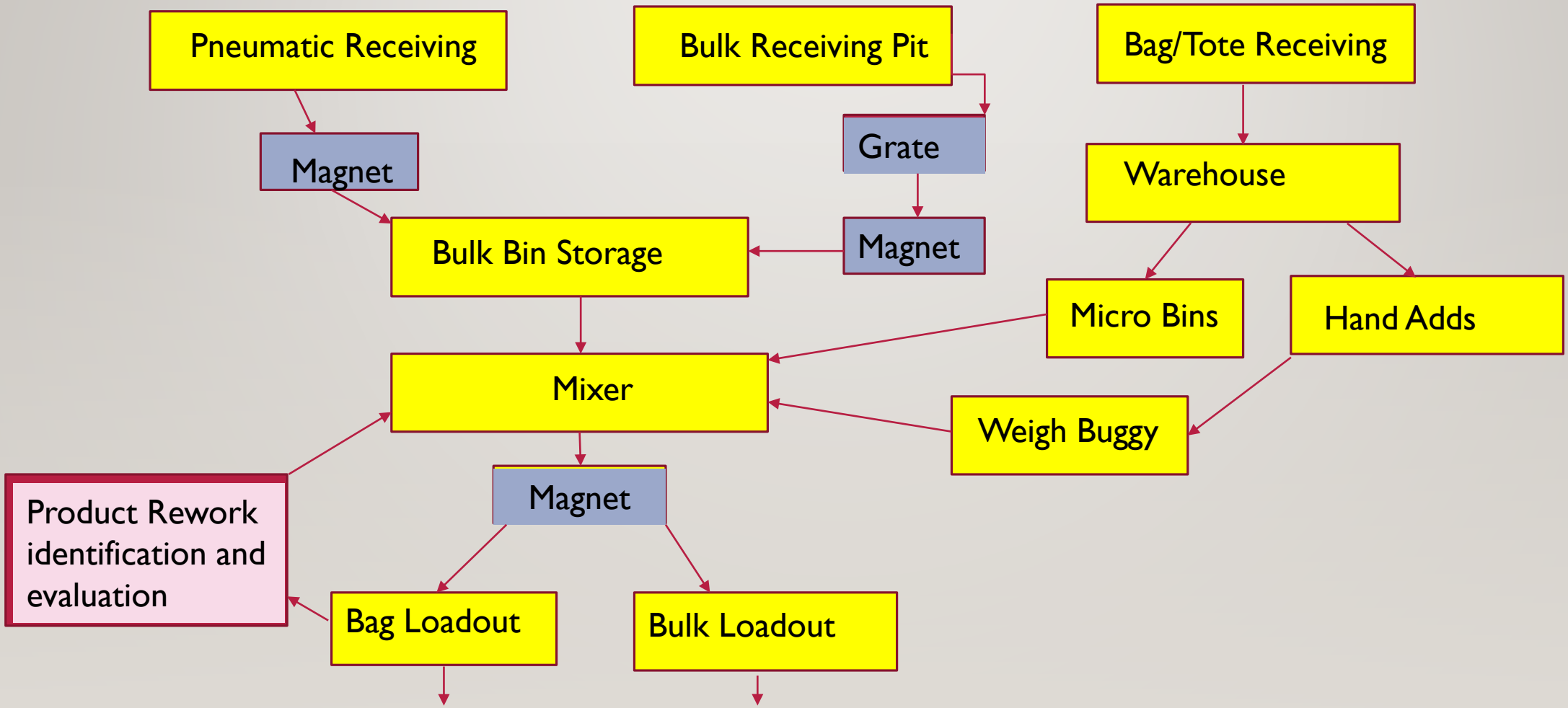
Food Safety Plan

Create a process flow diagram

A process flow diagram is ***not required*** but is a very helpful tool when looking at where the hazards are, and what prerequisite programs you have in place to handle any potential hazards in your facility. You will want to trace all pathways a product can go through from receiving to shipping.

ABC Company Process Flow Diagram



Conduct a Hazard analysis of your facility Listing List all of the Hazards (Biological, chemical and physical).

This is at the very heart of FSMA.
A detailed list of all known or reasonably foreseeable animal food safety Hazards
The hazard analysis assesses all potential animal food safety hazards that could be introduced within the production process flow. Hazards that are determined to be known or reasonably foreseeable. Hazard identification considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

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The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food
(2) The condition, function, and design of the facility and equipment
(3) Raw materials and other ingredients
(4) Transportation practices
(5) Manufacturing/processing procedures
(6) Packaging activities and labeling activities
(7) Storage and distribution
(8) Intended or reasonably foreseeable use
(9) Sanitation, including employee hygiene
(10) Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)

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With your Safety Team :

Talk a walk through of your facility and the surrounding grounds -- looking for any known or reasonably foreseeable hazard

Do a detailed review of the process flow diagram looking for item that might be used to control foreseeable hazards. Or where potential hazards may occur.

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After you list all of the Hazards you can come up with now you need to start evaluating each one as to:

1.) What is the Probability and Severity for this Hazard in your facility

2.) Determine whether or not this hazard needs a preventative control.

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Hazard analysis example

Example: You manufacture supplements for dairy cows and sheep at your facility.

One of the Hazards that you could list would be Copper in sheep feed.

First we want to evaluate it for Severity and probability

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Hazard analysis example

Severity: Copper can kill sheep

Severity level would be considered HIGH

We cannot alter or change the severity of a hazard. What we can do is use our standard operating procedures and policies to greatly reduce the probability of a known or reasonably foreseeable hazard occurrence in your facility. (your prerequisite program)

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Hazard analysis example

Now lets look at the probability that this will happen in your facility.

You have sop # 5.50 that explains: *how you use batch sequencing or Mixer flushing to minimize the risk of copper toxicity when manufacturing sheep feed.*

You have an sop # 5.70 that states: *all sheep feeds are made on Mondays and Wednesdays. In which mixers are flushed and inspected before manufacturing sheep mixes.*

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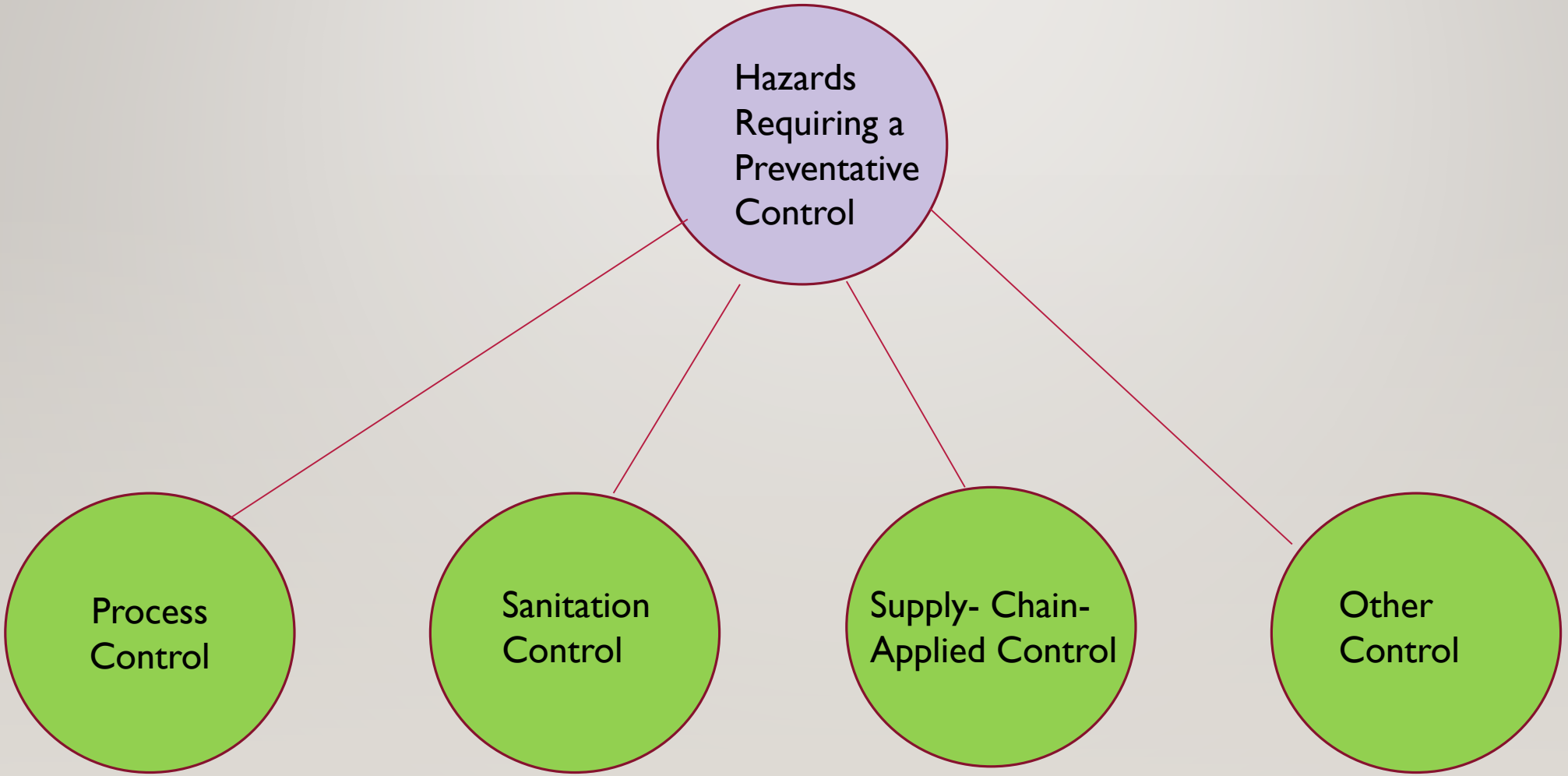
Hazard analysis example

One of the most important things to explain is the facilities history or experience in making these types of mixes.

Your history or complaint documentation says that you have never had a case of copper toxicity or carry over in the sheep feed that you manufacture. So your practices and polices are working.

Never undervalue your facility's past history of manufacturing safe animal foods.

Types of Preventative Controls



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Hazard analysis example

Possible Process Controls would be:

Documented flushing and inspection of mixer prior to manufacturing

Monitoring Inventory of all High copper Premixes pre and post manufacturing of sheep feed.

Having 2 people identify and check off the correct premix going into the sheep feed.

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Hazard analysis example

Possible Process Controls would be:

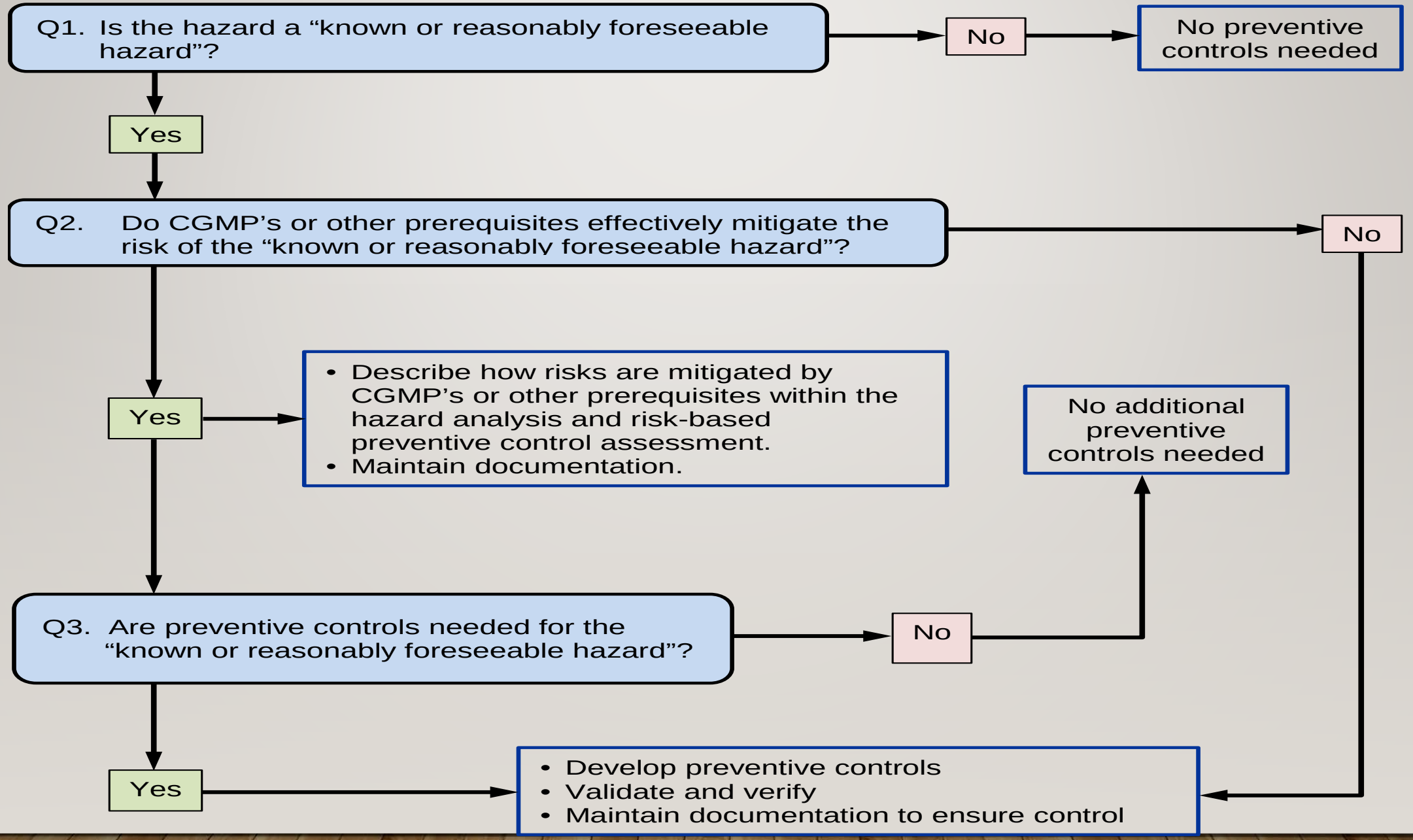
Establishing a written procedure for corrective actions if the Preventative control fails

Establish Verification Procedures

Create a Written recall plan.

RISK ASSESSMENT CHART

PROBABILITY SEVERITY	HIGH Immediate danger to health and safety of the animal or humans.	MEDIUM Probably will occur in time if not corrected, or probably will occur one or more times.	LOW Possible to occur in time if not corrected.	VERY LOW Unlikely to occur; may assume hazard will not occur.
HIGH Imminent and immediate danger of death or severe sickness.	1	2	4	7
MEDIUM Danger and sickness may be severe, but it is not imminent or immediate.	3	5	8	11
LOW Sickness or injury may occur, but impact is reversible.	6	9	12	14
VERY LOW Sickness or injury is minor.	10	13	15	16


Q1. Is the hazard a “known or reasonably foreseeable hazard”?
No
No preventive controls needed
Yes
Q2. Do CGMP’s or other prerequisites effectively mitigate the risk of the “known or reasonably foreseeable hazard”?
No
Yes
• Describe how risks are mitigated by CGMP’s or other prerequisites within the hazard analysis and risk-based preventive control assessment.
• Maintain documentation.
No additional preventive controls needed
Q3. Are preventive controls needed for the “known or reasonably foreseeable hazard”?
No
Yes
• Develop preventive controls
• Validate and verify
• Maintain documentation to ensure control

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Given the example that we just went over with copper in manufacturing sheep feed:

Do you think that this hazard requires a preventative control ?

Why or Why Not ?

TABLE 1. HAZARD ANALYSIS & PREVENTIVE CONTROLS

Identification			Evaluation					Prevention	
(1)	(2)		(3)	(4)	(5)	(6)	(7)	(8)	(9)
Ingredient or Processing Step	Identify known or reasonably foreseeable animal food safety hazards (8, C, P)		Determine the severity for the food safety hazard	Determine the probability for the animal food safety hazard	Determine the risk assessment for the food safety hazard	Does the hazard require preventive controls?	Justify the response in column 6	Appropriate control for Hazards Requiring a Preventive Control (PC)	Assigned Preventive Control (PC) Number
Packagig Materials	B	None							
	C	None							
	p	None							
Ingredient Animal Protein Products	B	BSE contamination	High	Very Low	Moderate (7)		1)BSE is negligible risk in the US; however, FDA regulations require facilities to ensure risk of contamination is controlled. 2)SOP-XX describes processes to ensure incoming ingredients are monitored for potential ruminant tissue contamination or content. 3) Verification from drivers that bulk load is not contaminated. 4) Supplier agreements maintained to assure incoming materials do not contain ruminant tissues.		
	C	None							
	p	Bone, other foreign materials	Low	Low	Moderate (12)		1) Incoming ingredients are inspected prior to receipt (SOP-XX). 2)Screens and magnets are used to remove potential physical food safety hazards (SOP-XX). 3) Customer complaints do not show concerns for foreign material contamination (SOP-XX).		

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Possible Analysis Documentation

Processing Step – Mixing Sheep Feed

Known or Reasonable foreseeable hazard – Chemical (Copper Toxicity in sheep feed)

Severity for the animal – High

Probability for the animal food safety Hazard – Low

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Possible Analysis Documentation

Does The Hazard Need a Preventative Control – No

Justify the Response – We use SOP # 5.50 and # 5.70 as our prerequisite program to minimize the probability of this happening in our facility.

Our Experience shows us that we have never had a copper toxicity or Carry over problem in any of the sheep feed we have manufactured. This brings us to the conclusion that our prerequisite program and employee training is working to minimize the probability of this hazard occurring.

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This is not a once and done thing it usually takes a few times going over things to find all of the important Hazards.

It is also an ongoing process that your PCQI needs to constantly evaluate especially if you put in a new piece of equipment, Start a new process or receive in a new ingredient. They all have to be evaluated for potential hazards and evaluate whether or not your prerequisite program covers it before you start using it.

- Preliminary steps that may be helpful to the hazard analysis process – **NOT REQUIRED BY RULE**
  - Assemble food safety team
  - Describe food and its distribution
  - Identify intended use/consumers
  - Develop flow diagram – helps identify where hazards may be introduced, be increased or occur in the process
  - Analyze flow diagram

What Is Required ?

You must prepare, or have prepared, and implement a written food safety plan

One or more **preventive controls qualified individuals** must prepare, or oversee the preparation of, the food safety plan

The written food safety plan must include:

- The written hazard analysis
- The written preventive controls as required
- The written supply-chain program (if needed)

What Is Required ?

- The written procedures for monitoring the implementation of the preventive controls as required
- The written corrective action procedures as required
- The written verification procedures as required
- The written recall plan as required

CGMP requirements and use of prerequisite programs may reduce the probability of occurrence of a "known or reasonably foreseeable hazard" and influence the hazard analysis

If compliance with CGMP requirements or use of prerequisite programs is used to make a determination that a hazard is not a "hazard requiring a preventive control," when otherwise it would be determined as such, then FDA likely will want to observe compliance with the CGMP requirement or review documentation that the prerequisite program is in place and effective

Resources to help identify hazards establish severity and probability

- Food and Drug Administration (FDA)
  - Recalls and Withdrawals
  - Reportable Foods Registry (RFR) for animal food/feed
  - Guidance for Industry
  - Established limits on contaminates in food and feed ie:

    Aflatoxin, Mycotoxins, Salmonella, Pesticide action levels, Etc.
- Centers for Disease Control and Prevention (CDC)
- European Food Safety Authority (EFSA)
- Minnesota Study on Possible Chemical or Biological Hazards in Feed manufacturing (AFIA or NGFA Member)

Hazard Analysis and Preventative Controls Determination Summary

- The Hazard analysis is the most important element of developing and effective food safety plan.
- Hazard analysis includes identification, evaluation (for both severity and probability), and determination of control measures.
- Outside resources are often needed to identify appropriate hazard analysis and control
- Hazard analysis is specific to the product, process and species type.

Questions ?

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