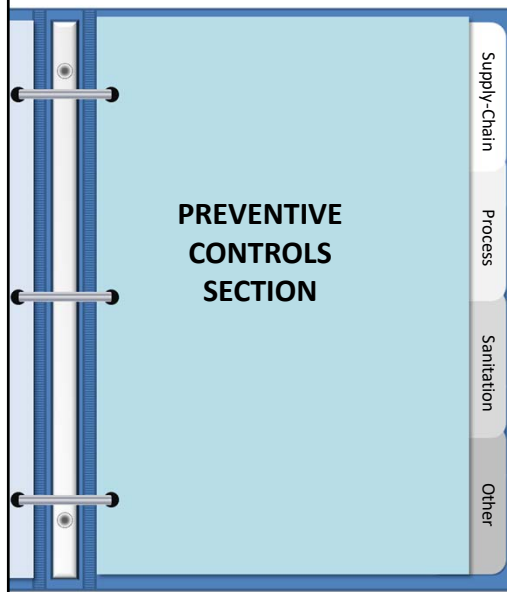


## Chapter 9

# SUPPLY-CHAIN-APPLIED CONTROLS



## Supply-Chain-Applied Controls Objectives



- In this chapter, you will learn:
  - The purpose of supply-chain-applied controls
  - Definitions associated with supply-chain-applied controls
  - The requirements of a supply-chain program
  - Documentation associated with the supply-chain program



## 21 CFR 507, Subpart E – Supply-Chain Program

- 21 CFR 507.105 – Requirement to establish and implement a supply-chain program
- 21 CFR 507.110 – General requirements applicable to a supply-chain program
- 21 CFR 507.115 – Responsibilities of the receiving facility
- 21 CFR 507.120 – Using approved suppliers
- 21 CFR 507.125 – Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
- 21 CFR 507.130 – Conducting supplier verification activities for raw materials and other ingredients
- 21 CFR 507.135 – Onsite audit
- 21 CFR 507.175 – Records documenting the supply-chain program



## Supply-Chain-Applied Controls: a Type of Preventive Control



## 21 CFR 507.3 - Definitions: “Receiving Facility”

- *A facility that is subject to subparts C (Hazard Analysis and Risk-Based Preventive Controls) and E (Supply-Chain Program) of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.*

## 21 CFR 507.3 - Definitions: “Supplier”

- *The establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.*

### 21 CFR 507.3 - Definitions: “Supply-Chain-Applied Control”

- *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.*

### When is a Supply-Chain Program Required?

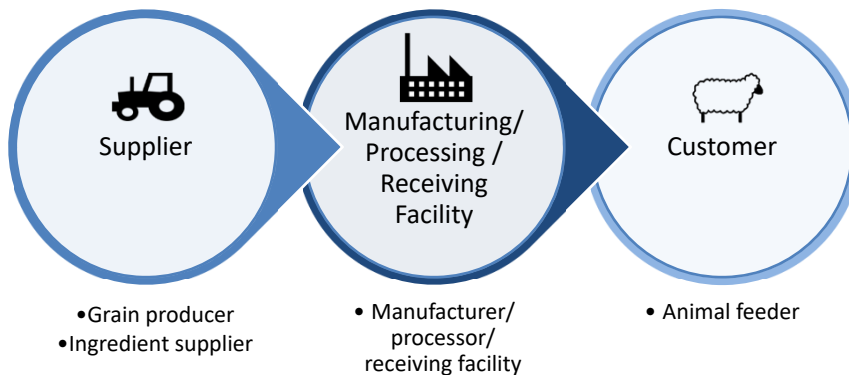
- Required if both of the following are true:
  - Facility has identified a *hazard requiring a preventive control* in a raw material or other ingredient
  - Facility determines that a supply-chain-applied control is necessary to control the identified hazard

## When is a Supply-Chain Program NOT Required?

- Not required if any of the following are true:
  - There is not a *hazard requiring a preventive control*
  - The receiving facility controls the hazard
  - A customer or downstream entity controls the hazard
  - An importer is in compliance with the foreign supplier verification program (FSVP) for the raw material or other ingredient
  - The food is supplied for research or evaluation use

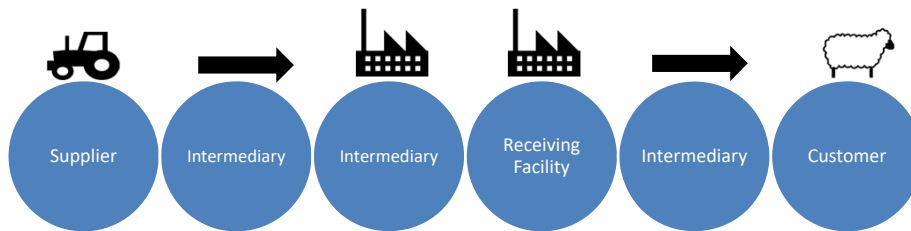


## Types of Supply Chains



Source: Microsoft Office Clipart

## Types of Supply Chains

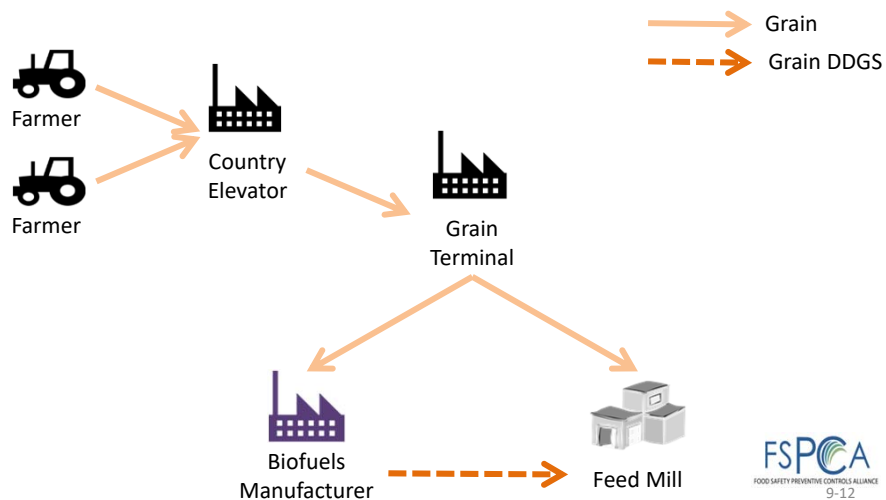


Source: Microsoft Office Clipart



## Exercise 9 Part 1

- Who is the receiving facility's supplier?



## Summary of Exercise 9 Part 1

---

- The supplier is the establishment that manufactures or processes the animal food, raises the animal, or grows the animal food without further manufacturing or processing by another establishment.
- Suppliers and intermediaries may be exempt from the Preventive Controls for Animal Food rule.



## Basics of a Supply-Chain-Applied Control

---

- Used as a preventive control when the ingredient or raw material supplier controls the hazard.
- Receiving facility is responsible for implementing the supply-chain program.
- Must be written and is considered part of the facility's Food Safety Plan.



## Basics of a Supply-Chain-Applied Control

---

- To meet Subpart E requirements, the supply-chain program must include:
  1. Approving suppliers
  2. Using only approved suppliers
  3. Having written procedures that the facility follows and documents to ensure they only receive ingredients/raw materials from approved suppliers
  4. Determining, conducting, and documenting appropriate supplier verification activities
  5. Implementing appropriate preventive control management components
  6. Documentation



## Basics of a Supply-Chain-Applied Control

---

- To meet Subpart E requirements, the supply-chain program must include:
  1. Approving suppliers
  2. Using only approved suppliers
    - May use unapproved suppliers on a temporary basis, as long as ingredient or raw material is subjected to appropriate supplier verification activities.





## Basics of a Supply-Chain-Applied Control

- To meet Subpart E requirements, the supply-chain program must include:
  3. Having written procedures that the facility follows and documents to ensure they only receive ingredients/raw materials from approved suppliers.
    - Must have *written procedures for receiving raw materials and other ingredients*.
    - Facility may develop these documents or rely on another entity for their development.
    - Facility can ensure and document written procedures are being followed or rely on another entity for this assurance and documentation.



## 21 CFR 507.3 - Definitions: “Written Procedures for Receiving Raw Materials and Other Ingredients”

- *Written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).*



## Supply-Chain-Applied Controls

---

- To meet Subpart E requirements, the supply-chain program must include:
  4. Determining, conducting, and documenting appropriate supplier verification activities
    - Receiving facility must determine supplier verification activities
      - Types of supplier verification activities:
        - Onsite audit
        - Sampling and testing
        - Review of a supplier's relevant food safety records
        - Other procedures or verification activities, if applicable
          - ❖ Alternative supplier verification activities for some suppliers
    - Must identify frequency of supplier verification



## Supply-Chain-Applied Controls

---

- To meet Subpart E requirements, the supply-chain program must include:
  4. Determining, conducting, and documenting appropriate supplier verification activities
    - Other entities may conduct and document supplier verification activities, but receiving facilities must review and assess applicable documentation
      - Restrictions on activities supplier can conduct
    - Activities must be completed before using raw material or other ingredients and periodically thereafter
    - Supply-chain program must provide assurance that a hazard requiring a preventive control has been significantly minimized or prevented



## Supply-Chain-Applied Controls

---

- To meet Subpart E requirements, the supply-chain program must include:
  4. Determining, conducting, and documenting appropriate supplier verification activities
    - Both the determination and conduction of activities must be written and meet Subpart F recordkeeping requirements.



## Factors for Supplier Approval and Verification

---

- Must consider:
  - Hazard analysis of the animal food
  - Entity applying controls to significantly minimize or prevent the hazard
  - Supplier performance
    - Supplier procedures, processes, and practices related to raw material or ingredient safety
    - Compliance of supplier to relevant FDA food safety regulations
    - Supplier's food safety history relevant to raw material or ingredients
  - Other appropriate factors, such as storage and transportation



## Onsite Audit Requirements (21 CFR 507.35)

- Only required if the hazard may cause serious adverse health consequences or death to humans or animals, but is a type of verification activity for other hazards
- Must be performed by a qualified auditor
- Audit must include (where applicable) a review of:
  - FDA food safety regulations
  - Supplier's written plan
  - Implementation of the written plan
- A food-safety-related compliance inspection by FDA or other agency may substitute for the onsite audit within one year of when an onsite audit would have been otherwise required.



## 21 CFR 507.3 - Definitions: "Qualified Auditor"

- *A person who is a qualified individual and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential auditors include:*
  - (1) A government employee, including a foreign government employee; and*
  - (2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter*



## Sampling and Testing

---

- May be conducted
  - by the supplier
  - at an outside lab, or
  - upon receipt
- Can communicate results in a COA
- Methods used must be fit for purpose
- Consult references on appropriate tests for different types of products
  - Indicator tests may be more useful than pathogen tests to assess effectiveness of overall controls



## Other Verification Activities

---

- Records reviews
- Requesting certificates of conformance
- Requesting continuing guarantees



## Basics of a Supply-Chain-Applied Control

- To meet Subpart E requirements, the supply-chain program must include:
  5. Implementing appropriate preventive control management components
  6. Documentation



## Management Components Appropriate for Ensuring the Effectiveness of Different Controls

	Process Preventive Control	Sanitation Preventive Control	Supply-Chain-Applied Control	Other Control
Monitoring	✓	✓		As necessary to satisfy the requirements of Part 507.
Corrective Actions and Corrections	✓	✓	✓	
Validation	✓			
Verification of Monitoring, Corrective Actions, and Implementation and Effectiveness	✓	✓	✓	

## Corrective Actions

---

- Written corrective action plan and records required
  - 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



## Summary of Records Required to Document the Supply-Chain Program

---

- Supply-chain program
- Compliance with foreign supplier verification program (if applicable)
- Supplier approval
- Written procedures for receiving raw materials and other ingredients
- Demonstrated use of written procedures for receiving raw materials and other ingredients
- Determination of appropriate supplier verification activities
- Determination that activity other than an onsite audit and/or less frequent audits are adequate
- Written results of an appropriate inspection by FDA or other agency when inspection substituted for an onsite audit
- Verification of control applied by an entity other than the direct supplier
- Facility's review and assessment of other entity's documentation
- Onsite audit report
- Sampling & testing results (if applicable)
- Review of supplier's relevant food safety records
- Other verification activities based on supplier performance and material risk
- Corrective action plan and records



## Exercise 9 Part 2

---

- Who can approve suppliers?
  - Only the receiving facility
- Can other entities provide help gathering material to help the receiving facility approve suppliers?
  - Yes, as long as it is the receiving facility who is approving suppliers
- Can other entities (that do not manufacture/process the product) provide the receiving facility a letter of assurance they have approved suppliers in order to maintain supplier anonymity?
  - No, only the receiving facility can approve the supplier
- Who can conduct supplier verification activities (e.g. onsite audits, sampling and testing, reviewing the supplier's animal food safety records)?
  - 1) The receiving facility or 2) another entity that the receiving facility has charged with the activity, as long as the receiving facility reviews and assesses appropriate documentation.



## Summary of Exercise 9 Part 2

---

- Only the receiving facility can approve suppliers.
- Verification activities are the responsibility of the receiving facility, but they may designate others to conduct those activities.





## Good Supply-Chain Business Practices

- Ensure supplier-initiated changes or changes to suppliers are communicated to the food safety team and PCQI
- Periodic re-evaluation
- Adjust program, as needed, to enhance food safety
- Reanalysis of the Food Safety Plan may be needed if deficiencies are identified



## Supply-Chain-Applied Control

### Maintain and review records

Identify a hazard requiring a preventive control during hazard analysis

Choose supply-chain-applied control as a preventive control

Receiving facility approves suppliers; establishes and oversees supplier verification activities

Conduct corrective actions if supply-chain-applied control fails

Review and reanalyze the Food Safety Plan as necessary

## Example of Implementation

---

### FOOD SAFETY PLAN FOR MULTI-SPECIES MEDICATED AND NON-MEDICATED FEEDS

Example



#### Livestock Food Example

<b>Hazard Analysis</b>	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 1. Hazard Analysis**


Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify <i>Known or Reasonably Foreseeable Hazards</i>	
Ingredients	C	Copper toxicity



Livestock Food Example				
<b>Hazard Analysis</b>	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 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify <i>Known or Reasonably Foreseeable Hazards</i>	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
Copper toxicity in sheep	I – High	B - Medium	Yes	Multispecies premixes used by facility, copper toxic to sheep




FSPCA  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE  
9-35

Livestock Food Example				
<b>Hazard Analysis</b>	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 1. Hazard Analysis		
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify <i>Known or Reasonably Foreseeable Hazards</i>	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
Copper toxicity in sheep	Supply-Chain-Applied Control - Control of copper level in sheep mineral premix	1




FSPCA  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE  
9-36

Livestock Food Example				
<b>Hazard Analysis</b>	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 2. Description of Preventive Controls				
Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
<i>Hazard Requiring a Preventive Control</i>	<i>Appropriate Control for Hazard Requiring a Preventive Control</i>	<i>Preventive Controls Number</i>	<i>Preventive Control Category</i>	<i>Parameters (if applicable)</i>
Copper toxicity in sheep	Control of copper level in sheep mineral premix	1	Supply-Chain-Applied Control	n/a




FSPCA  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE  
9-37

Livestock Food Example				
<b>Hazard Analysis</b>	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 2. Description of Preventive Controls				
Preventive Control(s)	Management Components			
	(1)	(6)		
<i>Hazard Requiring a Preventive Control</i>	Monitoring (if applicable)			
	What	How	Frequency	Who
Copper toxicity in sheep	n/a	n/a	n/a	n/a



FSPCA  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE  
9-38

Livestock Food Example			
<b>Hazard Analysis</b>	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 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
Copper toxicity in sheep	If improper Cu concentration in premix was used: 1) identify root cause, 2) re-train employee(s), 3) determine scope of problem by evaluating records and/or sampling and analyzing animal food, when necessary, 4) either blend, divert, hold-and-test, or dispose of affected animal food to prevent it from entering commerce, 5) reanalyze the Food Safety Plan, if necessary.	COA from supplier; Records reviewing the COA by supplier; Supplier approval and verification documentation; Record of annual audit

9-39

Livestock Food Example			
<b>Hazard Analysis</b>	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
Supplier Verification Activities	<ul style="list-style-type: none"> <li>○ Onsite audit</li> <li>○ Uses COAs for assurance of incoming Cu concentration</li> <li>○ Quarterly analysis of sheep trace mineral premix by the supplier to verify proper copper levels do not exceed the values established through the supply-chain-applied control via a certificate of analysis</li> <li>○ Reviewing the records of the supplier's Food Safety Plan for sequencing and flushing procedures to prevent carryover of copper into the sheep trace mineral premix</li> </ul>
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.

## Summary

---

- Required if hazard analysis identifies a *hazard requiring a preventive controls* and the facility chooses to control it with a supply-chain-applied control
- Key definitions include:
  - A *supplier* manufactures food, grows food or raises animals
  - A *receiving facility* is a manufacturer/processor
- Key requirements:
  1. Use approved suppliers
  2. Have written receiving procedures that it follows and documents
  3. Determine, conduct, and document appropriate supplier verification activities
- Documentation is a key element