National Grain and Feed Association

Supply-Chain Program

Food Safety Modernization Act Informational Seminar

March 10, 2016

SAFE ANIMAL FEED EDUCATION

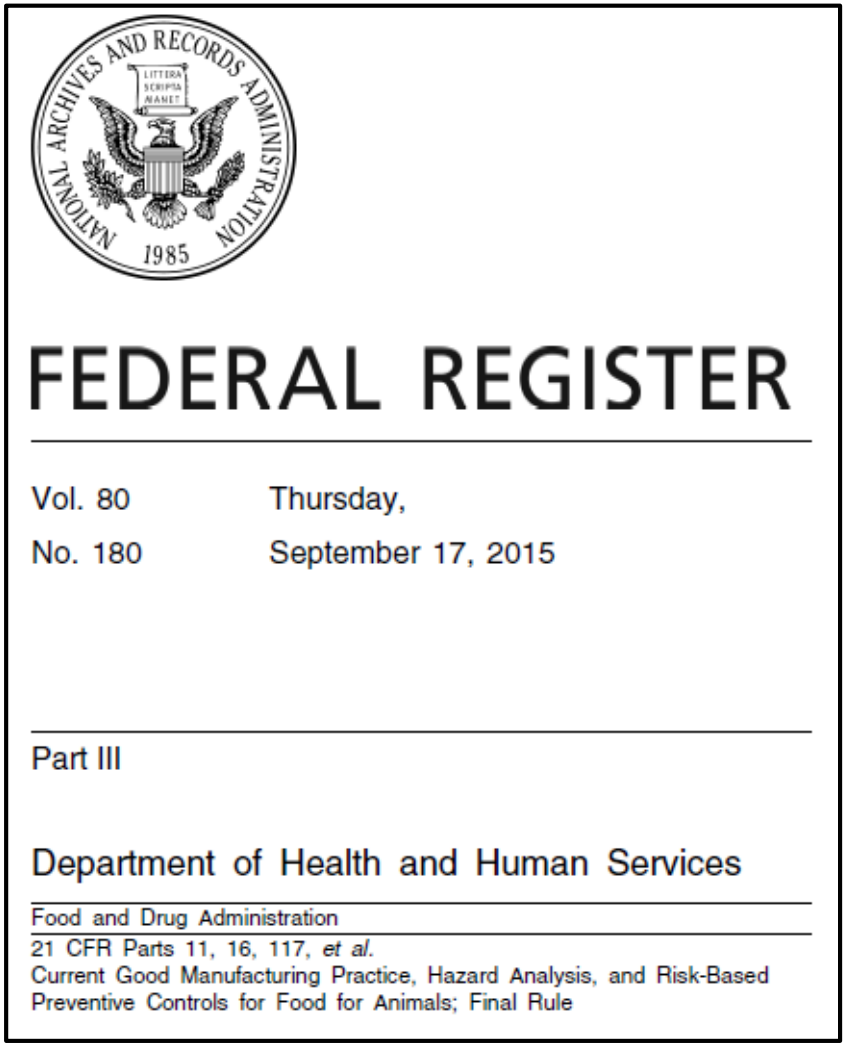
CALIFORNIA GRAIN & FEED ASSOCIATION

Disclaimer

- Some regulatory text from the final rule is included in this presentation, but not all text is provided! Also, in many instances the text provided is abridged to make it more brief and emphasize major concepts.
- Bottom line – this is a complicated rule and this presentation does not cover all aspects or all requirements!

Supply-Chain Program

- **PART 507—Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls for Food for Animals:**
  - Subpart A: General Provisions
  - Subpart B: Current Good Manufacturing Practices (CGMPs)
  - Subpart C: Hazard Analysis and Risk-Based Preventive Controls
  - Subpart D: Withdrawal of a Qualified Facility Exemption
  - **Subpart E: Supply-Chain Program**
  - Subpart F: Requirements Applying to Records That Must Be Established and Maintained



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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, 117, *et al.*
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule

Supply-Chain Program

- If it is determined that a “hazard requiring a preventive control” is associated with an incoming ingredient or raw material **and** that such a hazard will be controlled by the receiving facility’s supplier, then the receiving facility must implement a supply-chain program in accordance with Subpart E requirements

Supply-Chain Program Not Required

1. When no hazards requiring a supply-chain-applied control exist
2. When you (the receiving facility) control the hazard.
3. When a customer or downstream entity provides written assurance that they control the hazard
4. When an importer is in compliance with the foreign supplier verification program for the ingredient
5. The food is supplied for research or evaluation use

Supply-Chain Program Exemptions and Modified Requirements

- Exempt:
  - Farms
  - Facilities **solely engaged in the holding** of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, e.g., grain elevators
  - Facilities **solely** engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens
- Modified Requirements: Very Small Businesses

§ 507.3 – Definitions

- ***Receiving facility*** means a facility that is subject to subparts C [preventive controls] and E [supply-chain program] … and that manufactures/processes a raw material or other ingredient that it receives from a supplier
- ***Supplier*** means 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

§ 507.3 – Definitions

- ***Supply-chain-applied control*** means 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
- ***Qualified auditor*** means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditor include:
  (1) A government employee, including a foreign government employee
  (2) An audit agent of a certification body that is accredited in accordance with [FDA] regulations …

Subpart E – Supply-Chain Program

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

§ 507.105 Requirement to establish and implement a supply-chain program

(a)(1) … the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a **hazard requiring a supply-chain-applied control**

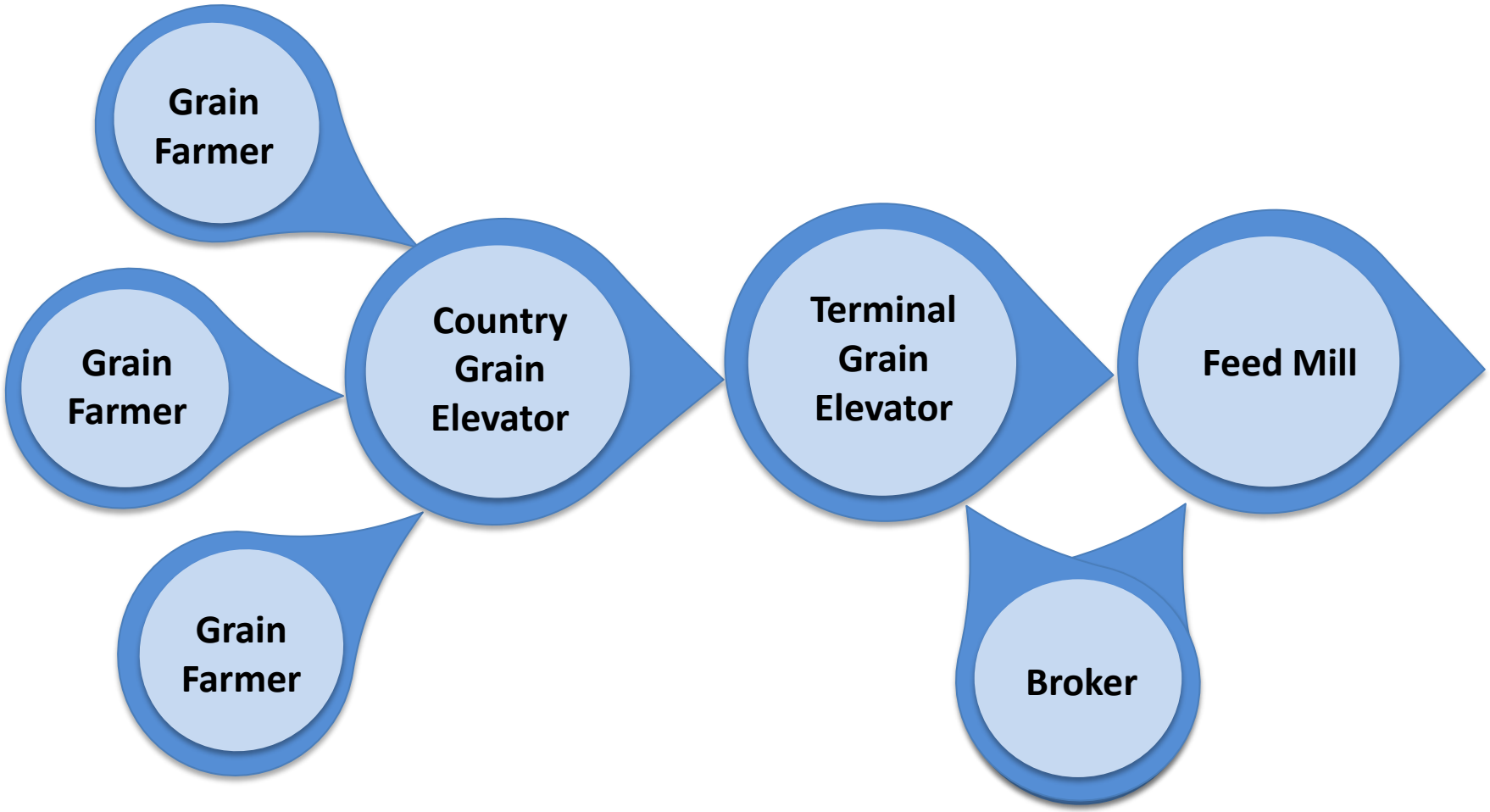
(2) A receiving facility that is an importer, and is in compliance with the foreign supplier verification requirements … need not conduct supplier verification activities for that raw material or other ingredient

(3) The **requirements** in this subpart **do not apply to animal food** that is supplied **for research or evaluation use**, provided ….

(b) The supply-chain program **must be written**

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier, … [the receiving facility must verify the control or obtain documentation verifying the control]

Who's The Supplier?



§ 507.110 General requirements applicable to a supply-chain program

(a) The supply-chain program must include:

(1) Using **approved suppliers** …

(2) Determining appropriate supplier verification activities …

(3) Conducting supplier verification activities as required …

(4) Documenting supplier verification activities as required …

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required …

§ 507.110 General requirements applicable to a supply-chain program

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) **Onsite audits**

(2) **Sampling and testing** of the raw material or other ingredient

(3) **Review of** the supplier's relevant **food safety records**

(4) **Other appropriate** supplier verification **activities** based on supplier performance and the risk associated with the raw material or other ingredient

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented

§ 507.110 General requirements applicable to a supply-chain program

(d) (1) … in **approving suppliers** and **determining the appropriate supplier verification activities** and the frequency with which they are conducted, **the following must be considered**:

(i) The **hazard analysis** of the animal food …

(ii) **The entity** or entities that will be **applying controls** for the hazards …

(iii) **Supplier performance**, including:

(A) The **supplier's procedures, processes, and practices** related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the **supplier's compliance** with those regulations

(C) The **supplier's food safety history**

(iv) Any **other factors** as appropriate and necessary, such as storage and transportation practices.

(e) If the … receiving facility determines … that the supplier is not controlling hazards, … the receiving facility must take and document prompt action

Supply-Chain Program General Requirements

Use approved suppliers

Determine supplier verification activities

Conduct supplier verification activities

Document supplier verification activities

When applicable, verify a supply-chain-applied control applied by an entity other than your supplier

§ 507.115 Responsibilities of the receiving facility

(a) (1) The receiving facility **must approve suppliers**

(2) … **the receiving facility must determine and conduct appropriate supplier verification activities** …

(3) An entity other than the receiving facility [e.g., corporate office, others] may do any of the following:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity

(iii) Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation

(4) The **supplier may conduct and document sampling and testing** of raw materials and other ingredients … for the hazard controlled by the supplier … provided that the receiving facility reviews and assesses that documentation ...

§ 507.115 Responsibilities of the receiving facility

(b) … a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier

(2) An audit conducted by its supplier

(3) A review by its supplier of that supplier's own relevant food safety records

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier …

(c) … a **receiving facility [may rely] on an audit** provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor …

§ 507.120 Using approved suppliers

(a) The receiving facility **must approve suppliers** … and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b) (1) **Written procedures** for receiving raw materials and other ingredients **must be established and followed**;

(2) The **written procedures … must ensure** that raw materials and other **ingredients are received only from approved suppliers** (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)

(3) **Use of the written procedures** for receiving raw materials and other ingredients **must be documented**

§ 507.125 Determining appropriate supplier verification activities

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d)

- **Hazard analysis** of the animal food
- **Entity applying controls**
- **Supplier performance**, including its:
  - procedures, processes, and practices
  - regulatory compliance
  - food safety history
  - other relevant factors

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients

(a) … **one or more of the supplier verification activities** … **must be conducted** for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter

(b) (1) … when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a **reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals**:

(i) **The appropriate supplier verification activity is an onsite audit of the supplier**

(ii) **The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter**

(2) The requirements of paragraph (b)(1) … do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled

§ 507.135 Onsite audit

(a) An **onsite audit** of a supplier **must be performed by a qualified auditor**

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan, if any, …

(c) (1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA …

(ii) For a foreign supplier, … an inspection by FDA or [an] authority of a country whose food safety system FDA has officially recognized

§ 507.135 Onsite audit

(c)(2) For inspections conducted by [an] authority of a country whose food safety system FDA has officially recognized …, the animal food that is the subject of the onsite audit must be… and the foreign supplier must be … under the regulatory oversight of such country

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with [FDA's Third-Party Certification Rule], the audit is not subject to the requirements in those regulations

§ 507.175 Records documenting the supply-chain program

(a) The records documenting the supply-chain program are subject to the requirements of subpart F

(b) The receiving facility must review the records listed in paragraph (c) of this section

(c) The receiving facility must document the following records as applicable:

- (1) The written supply-chain program
- (2) Compliance with the foreign supplier verification program requirements, if applicable
- (3) The approval of a supplier
- (4) Written procedures for receiving raw materials and other ingredients
- (5) Use of the written procedures for receiving raw materials and other ingredients
- (6) Determination of the appropriate supplier verification activities for raw materials and other ingredients

§ 507.175 Records documenting the supply-chain program

(c) The receiving facility must document ….

(7) Onsite audits conducted by qualified auditor and results

(8) Sampling and testing conducted as a supplier verification activity.

(9) Review of the supplier's relevant food safety records, and results

(10) Other appropriate supplier verification activities, if used

(11) Any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals is being adequately controlled

(12), (13), (14) Appropriate documentation of verification activities for a supplier that is "qualified facility," a farm or an shell egg producer

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations …

§ 507.175 Records documenting the supply-chain program

(c) The receiving facility must document …

(16) Actions taken with respect to supplier non-conformance;

(17) Verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier

(18) When applicable, the receiving facility's review and assessment of documentation from an entity other than the receiving facility that

(i) written procedures for receiving raw materials and other ingredients are being followed;

(ii) appropriate supplier verification activities for raw materials and other ingredients have been determined;

(iii) appropriate supplier verification activities for raw materials and other ingredients have been conducted;

(iv) sampling and testing is being conducted by the supplier; audits conducted by third-party audits are appropriate

(v) Appropriate verification activities for supply-chain applied controls by entities other than the receiving facility's supplier are being conducted

Compliance Dates for Supply-Chain Program

Situation	Compliance date:
A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule	Six months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule
A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule	The later of: September 17, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with this rule
A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule	Six months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule
A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule

Summary

- If it is determined that a “hazard requiring a preventive control” is associated with an incoming ingredient or raw material **and** that such a hazard will be controlled by the facility’s supplier, then the facility must implement a supply-chain program in accordance with Subpart E requirements
- A supply-chain program is **not** required if the facility determines there is no “hazard requiring a preventive control” associated with an incoming ingredient or raw material that will be controlled by the facility’s supplier **or** if the receiving facility controls the hazard

Supply-Chain Program

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