



**National Grain
and Feed Association**

Review of Records

Food Safety Modernization Act Informational Seminar

March 10, 2016

The logo for the California Grain & Feed Association, featuring a stylized orange and green graphic of a grain stalk and a map of California, with the text "CALIFORNIA GRAIN & FEED ASSOCIATION" in green.

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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!

Requirements Applying to Records

- **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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Department of Health and Human Services

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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

Subpart F – Requirements Applying to Records

- 507.200 Records subject to the requirements of this subpart
- 507.202 General requirements applying to records
- 507.206 Additional requirements applying to the food safety plan
- 507.208 Requirements for record retention
- 507.212 Use of existing records
- 507.215 Special requirements applicable to a written assurance

§ 507.200 Records subject to the requirements of this subpart

- (a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.
- (b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 (Public Information requirements)
- (c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request
- (d) The requirements of § 507.206 apply only to the written food safety plan

§ 507.202 General requirements applying to records

- (a) Records must:
 - (1) Be kept as original records, true copies ... or electronic records
 - (2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities
 - (3) Be accurate, indelible, and legible
 - (4) Be created concurrently with performance of the activity documented
 - (5) Be as detailed as necessary to provide history of work performed
- (b) All records must include:
 - (1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility)
 - (2) The date and, when appropriate, the time of the activity documented
 - (3) The signature or initials of the person performing the activity
 - (4) Where appropriate, the identity of the product and the lot code, if any
- (c) Electronic records that are established or maintained to satisfy the requirements of this part ... are exempt from the requirements of part 11 of this chapter (required records may be created and stored electronically)



§ 507.206 Additional requirements applying to the food safety plan

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification

§ 507.208 Requirements for record retention

- (a) (1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared
- (b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued ...
- (c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location
- (d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request

§ 507.212 Use of existing records

- (a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart
- (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing record

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