CHRISTIANSON & ASSOCIATES, PLLP

CERTIFIED PUBLIC ACCOUNTANTS AND CONSULTANTS

Knowledge. Experience. Vision.

A Biodiesel Producer's Guide to Understanding the Food Safety Modernization Act (FSMA)

Using this Guide:

As a summary of the FDA's rules, regulations, deadlines, and compliance requirements this guide can help you:

- ✓ **Know your FSMA Requirements**
- ✓ **Analyze their Impact**
- ✓ **Measure your Compliance Costs**
- ✓ **Determine your Best Path Forward**

Applicability

FSMA applies to the operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States and is required to register with the FDA.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

This means that if you are a biodiesel producer that sells glycerin later used as an ingredient in animal feed, the Food Safety Modernization Act is a regulatory program with which you will become quite familiar.

What is FSMA?

According to the FDA, FSMA "aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it." Their regulations put them in front of a number of industries with which they previously didn't interact.

Renewable fuels facilities producing feed co-products are no exception; and producers of ingredients used in or for animal food face new compliance burdens.

Phases of FSMA

As is a broad and multi-faceted law with multiple components taking effect at different times it is helpful to think of FSMA-Readiness in three phases –

Phase 1: cGMP and Pre-requisite Program Implementation

The first phase of FSMA compliance for animal food requires implementation of each of the categories of "Current Good Manufacturing Processes" (cGMP's) listed in Subpart B of the Code of Federal Regulations (21 CFR 507). Each of the cGMPs is also listed in Appendix A of this document.

Our consultants can write your cGMP compliance plan for you, or provide technical assistance and support while you write your own. In either case, a final cGMP review by our review team allows your facility to effectively demonstrate your status as "Phase 1 Ready."

Phase 2: Hazard Analysis/Preventive Controls and Written Food Safety Plan Development

The second phase of FSMA compliance involves adopting a written food safety program (WFSP). The WFSP includes, amongst other information, an analysis of all known reasonably foreseeable hazards, and a determination of whether each needs a preventive control to significantly minimize or prevent the risk of that hazard adulterating or contaminating the animal food at your facility.

After your hazard analysis is complete, we can look at the adequacy of justification for you how you determined a preventive control was or was not necessary – then incorporate both into a written food safety plan for you. Depending on the hazards you identify, we can also work with you to develop effective preventive control parameters, your product recall plan, and make potential considerations for a supply-chain program.

Phase 3: Ongoing Implementation, Verification, and Audit Readiness

The third phase of FSMA compliance is based on the reality that FSMA has deadlines, not finish lines.

FSMA is not a finalize-and-forget regulatory program or a one-and-done checklist that is filled out and sits on a shelf. While it is easy to think of implementing cGMPs and writing a food safety plan as simple projects to be checked off a to-do list, the reality is that the FDA expects its regulatory program to be an ongoing commitment by industry involving continuous monitoring, verification, and improvement.

Prior to FDA rules under FSMA, plants were generally only inspected for cause. FDA now has mandates to conduct routine inspections consisting of an audit-based review of records. The FDA intends for inspections to occur at least once by 2018 and at least every five years thereafter. Facilities that the FDA considers higher-risk will be inspected at a higher priority and frequency level than facilities considered low risk.

In recognition of that reality, you can get assistance preparing for audits of your programs under FSMA, or have us conduct a simulated/rehearsal audit of your programs in order to receive guidance and findings that will improve your audit readiness. We've even created a certification and accreditation program to make it easier for you to demonstrate to customers and regulators your commitment to produce safe and nutritious animal feed products.

By when do you need to Comply?

The size of your business determines your latest compliance deadline (regulatory requirements).

Key FSMA Compliance Dates and Deadlines			
Business Type	**Criteria**	**Subpart B and related requirements (cGMPs)**	**Subpart C (HARPC)**
Very Small Businesses	< $ 2.5 million in sales of animal food	September 17, 2018	September 17, 2019
Small Businesses	**< 500 Employees**	**September 18, 2017**	**September 17, 2018**
All Other Businesses	All other	September 19, 2016	September 18, 2017

Source: FDA Compliance Dates

However, the expectations of downstream customers buying glycerin determine how soon you'll opt to demonstrate compliance (market dynamics). You will find it helpful to talk with feedlots or your feed-based customers about what potential hazards they are concerned about, and evaluate what they will expect of you as one of their supplying plants.

Five Steps to Become FSMA Phase-1 Ready

Assembling a Team

Plant Name:
Mailing Address:

Primary FSMA Contact:
Direct Phone:
Email:

1. The owner, operator, or agent in charge of your facility is:
   _____
   _____

   (The name of person on your FDA facility registration)
   (Attach FDA facility registration as "Schedule A – FDA Facility Registration" if desired).

2. The members (and their positions) of your facility's food safety team will be:
   _____
   _____
   _____
   _____
   _____

   (Attach list of facility's food safety team with name, position, and short bio as "Schedule B – Food Safety Team")

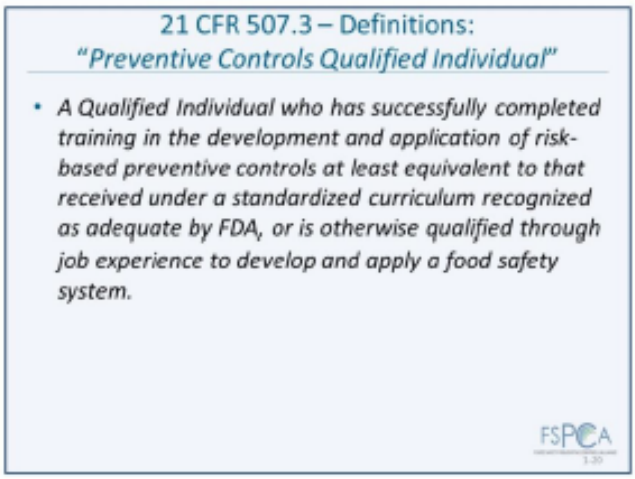
Obtaining a PCQI

3. The Preventive Controls Qualified Individual (PCQI) for your facility will be:

_____

_____

(Name and position)



(S)he will become PCQI by:

- ☐ **Attending PCQI training** – (recommended)
  - Course _____
  - Date _____
  - Attach Certificate of completion as "Schedule C – PCQI Qualifications"

- ☐ **Job experience** –
  - Include evidence to support sufficient job experience as "Schedule C – PCQI Qualifications"

4. Dates of National Biodiesel Board (NBB) Sponsored PCQI Trainings:

- ☐ **November 16-18 in St. Louis, MO** (immediately following the NBB Membership meeting)
- ☐ **January 18-20 in San Diego, CA** (coinciding and following the NBB annual conference)

NBB recently announced plans for hosting PCQI training, as required by FSMA. NBB is offering the trainings free of charge as a member benefit. It is offered to non-members as well, at a cost of $1,000. Those wishing to register should RSVP to Lola Helming at the NBB offices (lhelming@biodiesel.org). Christianson & Associates also has an FSPCA PCQI Lead Instructor on staff.

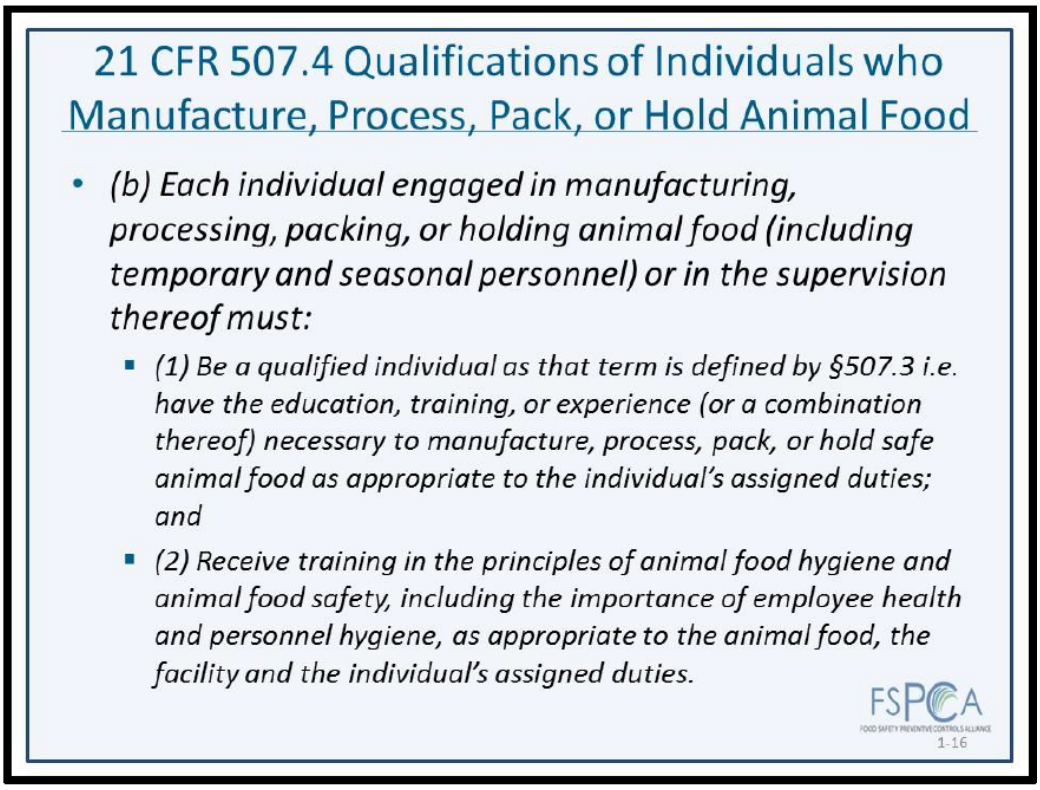
Meeting the Requirement for "Qualified Individuals"

5. You must ensure that all individuals who manufacture, process, pack, or hold food at your facility are:

   - Qualified to perform their assigned duties, and

   - Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personnel hygiene, as appropriate to the animal food, the facility, and the individual's assigned duties

     According to the FSPCA, this may include training by facility personnel, an external source, or the combination of the two. Training may occur on the job, in a classroom setting, or online. There is no specified frequency for training, but individuals should receive training prior to independently performing their assigned duties and refresher training should be made available as appropriate.



   - Supervisors must ensure compliance with training to the duties of the qualified individual and the training in principles of animal food hygiene and animal food safety.

   - Records must be established and maintained to document that the training in animal food hygiene and animal food safety occurred.

6. List all individuals/positions at your facility that will need to meet the "qualified individual" requirement (individuals who manufacture, process, pack, or hold food):

_____
_____
_____
_____

(Name and position – Attach Organization Chart highlighting these positions as "Schedule E – Org Chart")

7. The following are examples of documentation that could be used to help substantiate that "qualified individuals" in your facility have the education, training, or experience necessary to manufacture, process, pack, or hold safe animal food according to their assigned duties:

- ☐ Accurate job descriptions detailing employee responsibilities
- ☐ Transcripts or other documentation of training on job duties
- ☐ Training records/course completion certificates for animal food hygiene and safety
- ☐ Resumes or other documentation of job experience
- ☐ Documented training (e.g. administered by video or supervisor)
- ☐ Other (Specify):

_____
_____
_____

a. Please provide job descriptions for each person you identified in your org chart as needing to meet the "Qualified Individual" requirement, attaching them as "Schedule F – Job Descriptions."

b. Describe how you will use the records in "7" to demonstrate existence of education, training, and experience for each of the positions in "7a."

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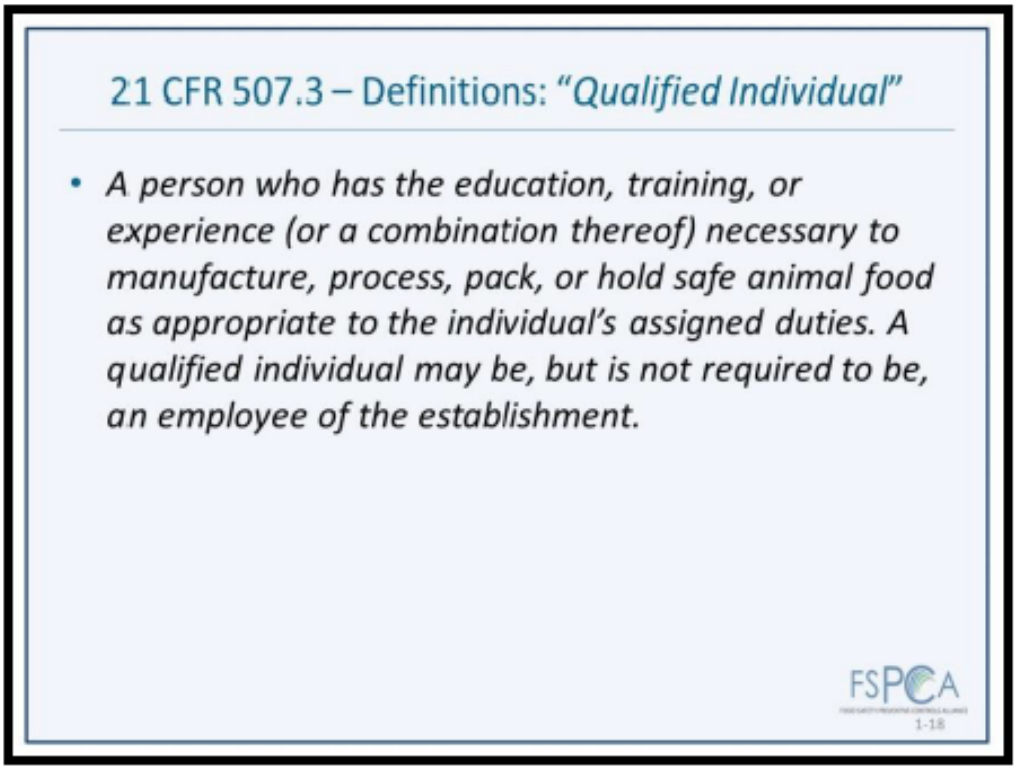

21 CFR 507.3 – Definitions: "Qualified Individual"
• A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
FSPCA
1-18

Developing Auditable SOPs supporting cGMP implementation

cGMPs help establish the basic environmental and operating conditions necessary to support the forthcoming "Hazard Analysis and Risk-Based Preventive Controls" (HARPC) and Written Food Safety Plan requirements.

Even though your facility likely already operates in alignment with a number of industry standard cGMPs, it's important to give these your full attention since they are now part of a much larger regulatory framework that places you under the oversight of the Food and Drug Administration (FDA).

Because cGMPs are typically "generally observable activities," documentation to support their implementation is not a *requirement*; however, you may find that records are a *necessity* for many of them for which are exceedingly difficult to substantiate without. As such, most facilities generally have an employee training program and written Standard Operating Procedures (SOPs) to manage the cGMPs and document the results of the corresponding programs.

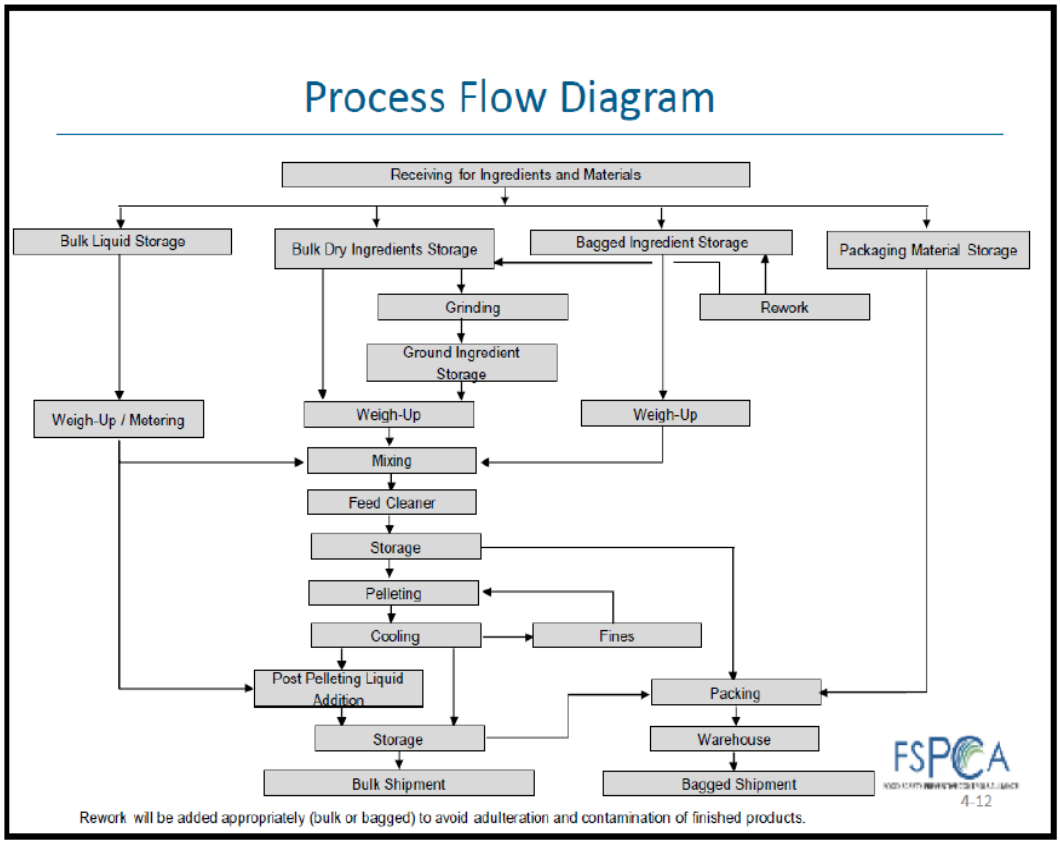
8. Prerequisite or quality assurance programs or certifications already employed in your facility: (e.g. AIB , Safe Feed/Safe Food, HACCP)

   _____
   _____
   _____
   _____
   _____
   _____

9. Please attach the following items as "Schedule D – Process Notes"

   - ☐ Block/Process Flow Diagram
   - ☐ List of Ingredients
   - ☐ List of Feeds Manufactured
   - ☐ Description of Manufacturing Process

Example:



Our consultants can write your cGMP compliance plan for you, or provide technical assistance and support while you write your own.

10. cGMP Program Planning Questions:

- ☐ What is the degree to which you intend to manage the process internally and the level to which you hope to outsource some of that work?

  _____
  _____
  _____
  _____
  _____
  _____

- ☐ What types of competing priorities and ongoing commitments of time and resources might get in the way of timely, proactive implementation?

  _____
  _____

- Who are the primary buyers of your glycerin and co-products? Have they made you aware of any special requirements they expect you to fulfill as part of their own process of becoming compliant with FSMA?

  _____
  _____
  _____
  _____
  _____
  _____
  _____

Options for Completing a cGMP Review

A final cGMP review by our review team provides you a set of fresh eyes to do a full review from the technical compliance perspective and allows your facility to effectively demonstrate your status as "Phase 1 Ready."

Full cGMP Plan: Based on information you make available to us, C&A van construct a cGMP plan tailored to the specifics of your facility. This cGMP plan will allow you to ensure you take actions necessary to demonstrate adequate and ongoing execution of the FDA's cGMPs. Because your facility is ultimately responsible for Federal Regulations compliance, your team will have the chance to review the cGMP plan and evaluate it prior to final acceptance. The back-and-forth will allow you to work with us to make sure the plan we draft for you is satisfactory.

cGMP Validation Service: Our team of experts is available to provide you custom research, analysis, and interpretation to assist you with applying industry principles to facility specific situations. This back and forth will help ensure you identify the risks of under compliance and the burdens of over compliance in order to find the right balance for meeting the FDA's expectations for your facility. We can perform a gap analysis and work with your team in order to validate and augment your existing cGMP plan. Your plan may be complete, or in process as a part of this option.

What if you don't want to Comply with these Regulations because of Perceived Cost or Burden?

Regulatory changes can have a significant impact on the market. The key to minimizing the cost and burden of the transition is proactive planning and management. However, when you couple the limited value of glycerin as a co-product and its excess supply in the market you may re-assess your market options.

How much money are you recovering from selling glycerin (additional revenue and avoided disposal costs), and what would it cost you to become FSMA-ready and remain FSMA-compliant?

Answering this question is helpful for identifying your strategy moving forward toward the FDA's compliance deadlines.

If you're wondering what your options for FSMA compliance are, it pays to work with a leader who understands your industry. Christianson and Associates can help you assess your readiness and determine the amount of assistance you will need to become compliant, prior to the statutory

Our **FSMA-Readiness Program** and compliance team can provide you with training, resources, and technical assistance to make the transition to the FDA's brand of formal food safety. We have an FSPCA PCQI Lead Instructor on staff and have knowledge that can help you navigate the FDA's requirements, assess your readiness, and determine the amount of assistance you will need to become compliant prior to the statutory deadlines.

Our **business assistance team** can help you assess the value propositions of different strategies to managing FSMA implementation. We can also help you evaluate potential options for avoiding a compliance obligation. If so, our team of grant writers with REAP and VAPG specific experience can help you secure funds for certain types of capital upgrades.

How do you assess costs and benefits of various feed market avoidance strategies?

Can you designate your glycerin for industrial use only/not for use in food or feed to avoid oversight by the FDA?

If so, what's your disposal cost when you encounter a situation where you can't sell your full quantity at a competitive price when limiting yourself to a smaller market segment?

Is it feasible to upgrade your ability to further refine your glycerin to a higher quality, non-waste stream for pharmaceutical use?

Depending on the ownership structure of your plant, you want help applying for a value added producer grant covering up to 50% of the costs of making necessary capital modifications to complete the project.

What would it cost to retrofit your plant to burn/incinerate the glycerin for process energy/boiler heat?

A USDA REAP Energy Replacement Grant would potentially cover up to 25% of the cost of doing so.

These are examples of a couple of strategies available to those who determine burdens of FSMA-compliance outweigh the benefits of selling glycerin into animal feed markets.

Our FSMA team is available to help you determine your overall approach to FSMA-compliance or avoidance. To get the most benefit, contact us -- before the pressure builds to have a comprehensive written food safety plan correctly formalized and implemented.

Items for Enclosure

- ☐ Schedule A – FDA Facility Registration"
- ☐ Schedule B – Food Safety Team
- ☐ Schedule C – PCQI Qualifications
- ☐ Schedule D – Process Notes
- ☐ Schedule E – Org Chart
- ☐ Schedule F – Job Descriptions
- ☐ Schedule G – cGMP Analysis

Non-Disclosure of this Guide and Associated Information

This information was gathered from a number of resources including the FDA, the CFR, the FSPCA, the RFA, and KSU. While a significant amount of this information may be publicly available in various forms or manners, this guide (and documentation associated with it) is considered confidential and proprietary. It should only be disclosed or shared as permitted by the non-disclosure agreement between your company and Christianson & Associates, PLLP.

Summary

While this information is intended to assist you developing, implementing, validating, and monitoring a plan to become FSMA-ready and FSMA-compliant, it is important to remember that it's general in nature and that your facility is ultimately responsible for Federal Regulations compliance. The parameters of your facility's operations are unique; have a Preventive Controls Qualified Individual and other industry experts assist you with transforming standardized principles into specific procedures.

1. **Learn the Basics**: Familiarize yourself with the general scope and requirements of FSMA.

2. **Build your team**: Which key staff will be involved with FSMA implementation, monitoring, and oversight?

3. **Qualify your staff**: Who and how many on this team do you want to have PCQI trained and credentialed? How soon can you make it happen?

4. **Assess your current capabilities**: Proactive management of this new relationship with the FDA is essential to minimize the cost and burden of the regulatory transition. Don't let competing priorities get in the way of projects that demand attention today. Evaluate your plant to approximate the situation, status, and time and resources likely to be required.

5. **Partner with an expert**: Cookie-cutter templates are essential for ensuring something isn't overlooked, but they're definitely not sufficient for addressing plant-specific considerations for your unique set of operational parameters and practices.

6. **Develop your strategy**: Put together a plan for getting all the required components in place. Under-compliance with new regulations is always a concern. But over-compliance comes with its costs as well; you don't want to have to buy a cannon to kill a mosquito.

Our multi-phase services are designed to meet expectations specific to the FDA's tiered compliance deadlines. They start with technical assistance and can culminate with a full quality assurance, audit package, and a C&A facility certification you can provide customers who use you as a supplier.

After you have added your answers to this guide and noted any questions you have about particular issues in the margins or in another area, please **send a completed copy to pcleary@christiansoncpa.com to get a no-cost initial consult by phone or email.**

Your Name: _____

Company/Title: _____

Phone: _____

Email: _____

Appendix A – cGMP Scoresheet

Because of our experience in the biofuels industry, we're being asked a number of questions about what it will take managers to demonstrate their biodiesel plant's commitment to feed safety to regulators in the new era of FDA oversight.

Are you ready for the first phase of compliance requirements under the Food Safety and Modernization Act (FSMA)?

Our Phase 1 FSMA Readiness Program (focused on technical assistance and expert support for cGMPs) was created to help you address your most immediate compliance needs while developing and expanding your resources for ongoing compliance.

As you review the cGMPs, assess your current level of compliance with the requirement using a 0-5 scale, where a 0 represents adequate, a 5 represents inadequate.

The higher the score assigned to the requirement, the more urgent attention you will need to provide in addressing the issue.

While basic in format, this will help you conduct a preliminary inventory and identify those cGMP items that will require the most attention at your facility. It is a good way to start evaluating the degree of your plant's readiness for FSMA prior to your deadline.

cGMP Area	Score
1) § 507.14 Personnel	_____
2) § 507.17 Plant and grounds	_____
3) § 507.19 Sanitation	_____
4) § 507.20 Water supply and plumbing	_____
5) § 507.22 Equipment and utensils	_____
6) § 507.25 Plant operations	_____
7) § 507.27 Holding and distribution	_____
Total	_____

§ 507.14 Personnel.

(a) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.

(b) The methods for conforming to hygienic practices and maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

507.14 Personnel -- **Total**

§ 507.17 Plant and grounds.

☐ (a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

☐ (b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:

(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (*e.g.,* steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;

(4) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned; and

(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.

☐ (c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:

(1) Using protective coverings where necessary and appropriate;
(2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and
(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

☐ 507.17 Plant and grounds -- **Total**

§ 507.19 Sanitation.

☐ (a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.

☐ (b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and
(2) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

☐ (c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

☐ (d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:

(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in laboratory testing procedures;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in the plant's operations.

(2) Toxic materials described in paragraph (d)(1) of this section (*e.g.,* cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and

(3) Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.

☐ (e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

☐ (f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.

☐ 507.19 Sanitation -- **Total**

§ 507.20 Water supply and plumbing.

☐ (a) The following apply to the water supply:

(1) Water must be adequate for the operations and must be derived from an adequate source;

(2) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities;

(3) Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and

(4) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

☐ (b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

☐ (c) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.

☐ (d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

☐ (e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

☐ 507.20 Water supply and plumbing **– Total**

§ 507.22 Equipment and utensils.

☐ (a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:

(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

☐ (b) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.

☐ (c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.

☐ (d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

☐ (e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.

☐ 507.22 Equipment and utensils – **Total**

§ 507.25 Plant operations.

(a) Management of the establishment must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;

(3) Animal food-packaging materials are safe and suitable;

(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;

(6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;

(7) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(8) All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.

(b) Raw materials and other ingredients:

(1) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize contamination; and

(iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and

(3) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

☐ (c) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:

(1) Animal food must be maintained under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(2) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (*e.g.,* heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a $_w$) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;

(6) Animal food that relies principally on the control of water activity (a $_w$) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe a $_w$ level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

☐ 507.25 Plant operations – **Total**

§ 507.27 Holding and distribution.

☐ (a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and

(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.

☐ (b) The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the animal food product for the intended animal species.

☐ (c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.

☐ (d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

☐ (e) Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.

☐ 507.27 Holding and distribution – **Total**

Appendix B – FSPCA cGMP Assistance Booklet

CHAPTER 2. Current Good Manufacturing Practice

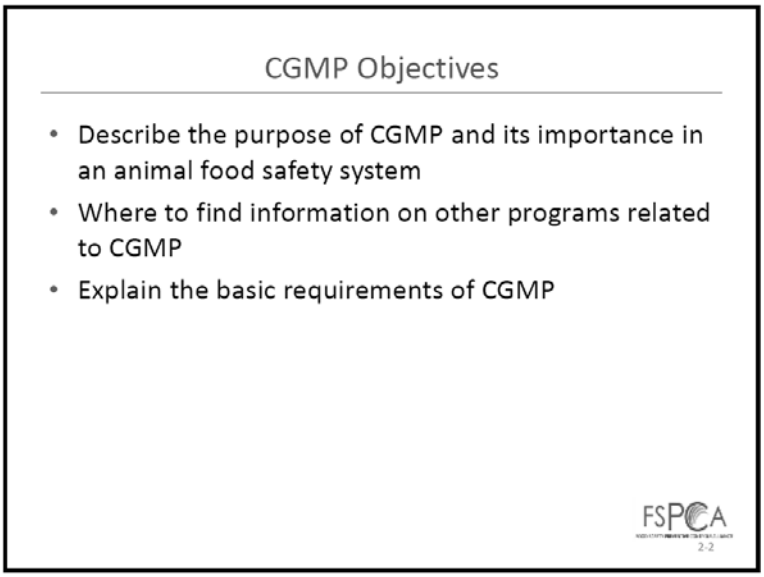
CGMPs are generally observable activities that do not require documentation.

There is a great amount of flexibility in the CGMP requirements, as noted by terms such as 'as necessary' and 'when appropriate.'

Slide 1

This chapter describes the required components of 21 CFR 507 Subpart B: Current Good Manufacturing Practice or CGMP. CGMP requirements apply to registered establishments involved in the manufacturing, processing, packing, and/or holding of animal food, with the exceptions of:

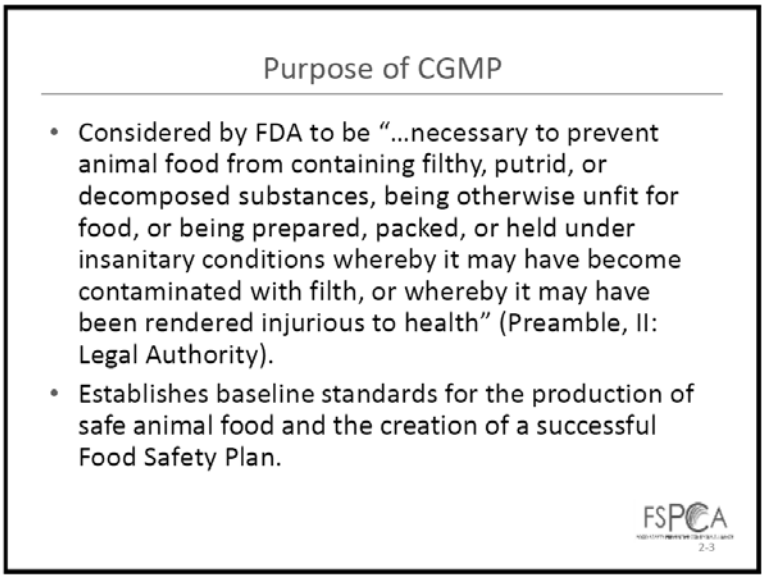
- Establishments soley engaged in the holding and/or transportation of raw agricultural commodities (e.g. grain and oilseeds.)
- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and
- Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed)



Slide 2

This chapter will address the following objectives:

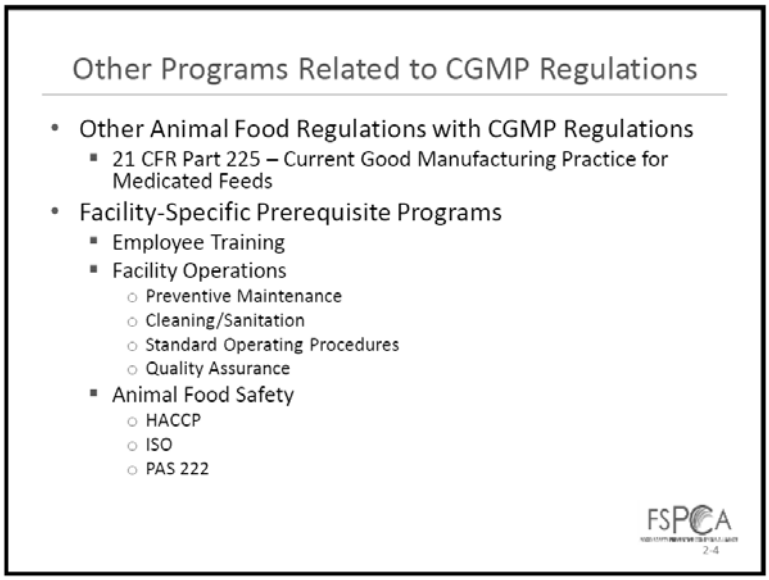
- Describe the purpose of Current Good Manufacturing Practice requirements and their importance in an animal food safety system
- Where to find information on other programs related to CGMP
- Explain the basic requirements of CGMP



Slide 3

FDA describes the purpose of Current Good Manufacturing Practice requirements in the preamble to the final rule. CGMP requirements are considered by FDA as being *"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 contminated with filth, or whereby it may have been rendered injurious to health."* The CGMP requirements in subpart B are intended to serve as baseline standards for producing safe animal food across all types of animal food facilities, including pet food facilities.

The CGMPs include flexibility, where appropriate, to address the diversity of facilities, the wide range of animal food activities a facility might engage in, and the potential safety risks posed by some animal foods. These flexible CGMP requirements can be applied in various animal food production settings. The flexibility in these provisions is indicated by phrases such as "when necessary," or "as appropriate."

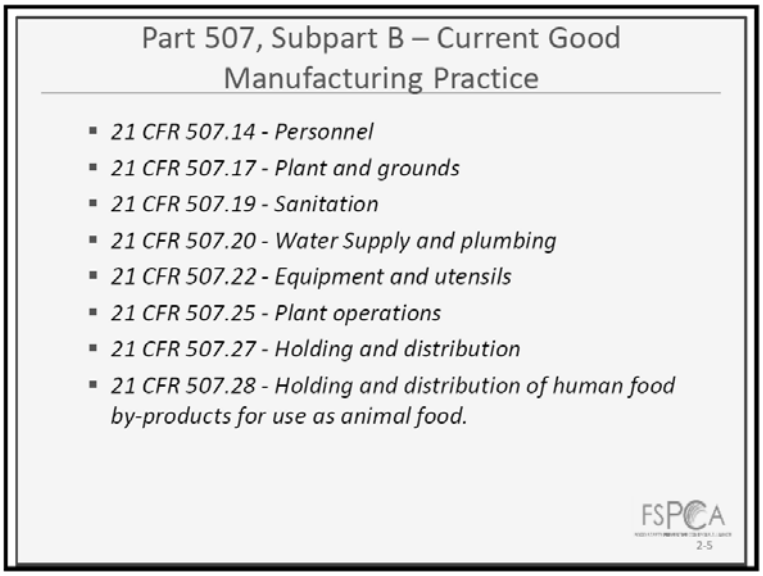


Slide 4

There are a number of other programs that are related to, and have similar provisions as the CGMP requirements found in 21 CFR part 507, subpart B. As an example, FDA implemented CGMP requirements for the manufacture of medicated feeds (21 CFR Part 225) in the 1970's. The specific requirements of the medicated feed CGMP, including the control of drug components, laboratory assays or controls, and the requirement to maintain a complaint file remain in effect. The medicated feed CGMP establish requirements beyond those and for different purposes than the CGMP discussed in this chapter. However, there are notably comparable sections, such as the design and maintenance of buildings, plant and grounds, and equipment to manufacture safe animal food.

In addition to the medicated feed CGMP requirements, there are other programs that animal food manufacturing facilities may already voluntarily utilize as best practices or as prerequisite programs. Many facilities have employee training programs in place to meet the requirements of non-food safety regulations. Facilities may also have preventive maintenance programs, cleaning or sanitation schedules and programs, Standard Operating Procedures (SOPs), and quality assurance programs. These types of programs are typically directed to maximize product quality, personnel safety, and facility efficiency, but the standards they set forth may very well meet the requirements of the CGMP required by FSMA.

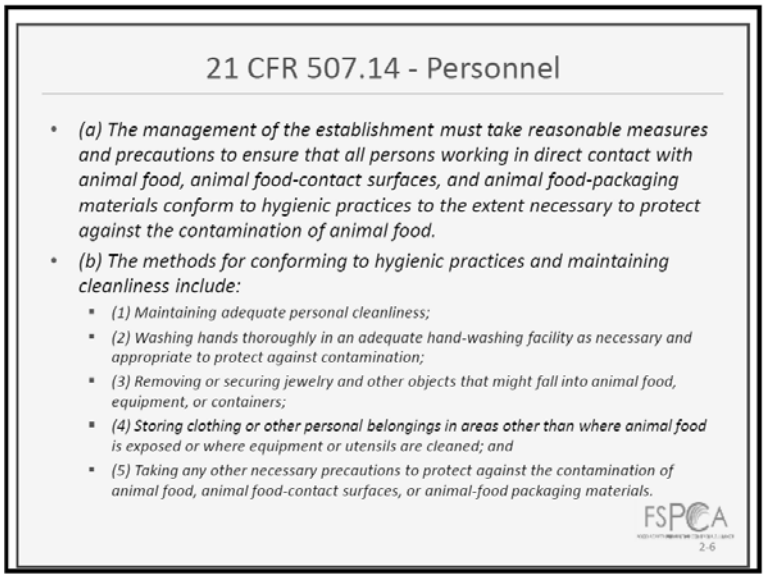
Furthermore, some facilities have in place proactive programs already addressing animal food safety. Some common programs used in the animal food industry include HACCP, ISO 22000, and PAS 222. Under these programs, facilities may meet the requirements for CGMP. Each facility is different, and the *Preventive Controls for Animal Food* rule is very flexible, so there are many ways that these programs can be used to meet the requirements of the rule. The ultimate goal is that all requirements are met and safe animal food is produced.



Plant is defined as the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food. It is also referred to and is synonymous with facility as it relates to this training.

Slide 5

The main purpose of this chapter is to familiarize participants with the contents of 21 CFR part 507, subpart B. The CGMP requirements in subpart B have 8 different sections, including *Personnel, Plant and grounds, Sanitation, Water supply and plumbing, Equipment and utensils, Plant operations, Holding and distribution,* and *Holding and distribution of human food by-products for use as animal food.*



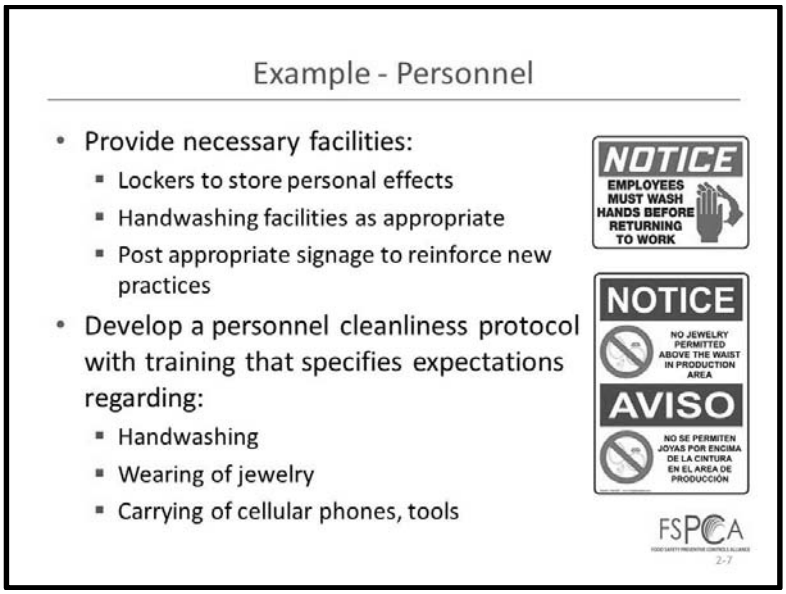
Slide 6

In the discussion of 21 CFR part 507, subpart A in Chapter 1, some requirements regarding personnel were introduced. Specifically, all individuals engaged in manufacturing, processing, packing or holding animal food subject to the *Preventive Controls for Animal Food* rule must meet the definition of a *Qualified Individual*, and receive documented training (CFR 21 507.4). The CGMP requirements further describe the specific expectations for those *Qualified Individuals* who manufacture, process, pack, or hold animal food.

The personnel section states that the management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food. For example, management expectations for personnel working in a livestock animal food manufacturing facility might allow clothes that are dusty from working in the facility, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials. The extent of hygienic practice necessary also depends on the animal food being manufactured and the intended use of the animal food. For example, a pet food facility handling raw meat ingredients may have a more stringent procedure for employee hand-washing than a feed mill only handling dry grains.

The methods for conforming to hygienic practices and maintaining cleanliness include:

- Maintaining adequate personal cleanliness
- Washing hands thoroughly in an adequate hand-washing facility
- Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers
- Storing clothing or other personal belongings away from animal food or equipment cleaning areas
- Taking any other precautions considered to be necessary to protect against contamination of animal food, contact surfaces, or packaging materials



There is flexibility provided for how establishments meet these requirements. For example, in the preamble of the rule, FDA states that it recognizes that there may be some situations where hand-washing facilities are not readily available, and that the use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances. In addition to adequate and accessible hand-washing facilities, an establishment may post appropriate signage to reinforce hand-washing practices and establish a training program to emphasize the importance of hand-washing.

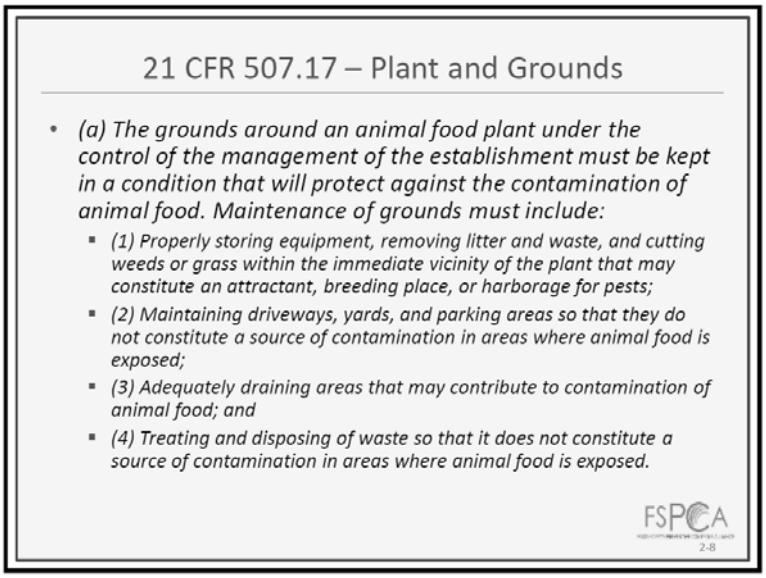
Slide 7

Regarding personal belongings, an employer may provide lockers or other storage areas for personnel to store clothing or other personal items in areas away from where animal food is exposed or where equipment is cleaned.

To conform to the personnel requirements, establishments need to ensure that adequate hand-washing facilities are available and that hygienic and cleanliness practices are in place to protect against the contamination of animal food to the extent necessary.

A personnel training program could be implemented to emphasize the importance of hand-washing, the potential hazards associated with wearing different types of jewelry, and the chosen policy on the carrying and use of cell phones and tools within the facility.

Ultimately, there are different ways that an employer can comply with these requirements. How management meets the requirements can vary, so long as the requirements of 21 CFR 507.14 are met.



The grounds are considered to be under the control of management when the property/land is owned or leased by the facility or used with permission.

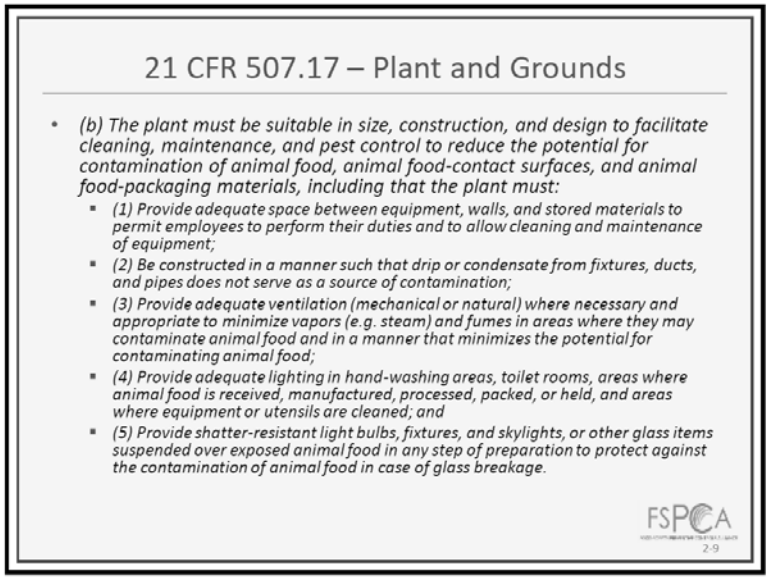
The grounds are close enough to be "around" the plant when they could impact plant operations. Public right of ways or neighboring properties under different ownership would not be considered under the control of the management.

Slide 8

The next three slides focus on the requirements of 21 CFR 507.17 – Plant and Grounds. Each slide is dedicated to a specific set of requirements.

The first set of provisions relate to the condition of grounds around the establishment. The primary requirement is that the condition of the grounds protect against the potential contamination of the animal food. As such, maintaining the grounds must include:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass that may attract or harbor pests
- Maintaining driveways, yards, and parking areas such that they will not contribute to contamination of exposed animal food
- Adequately draining areas that may contribute to contamination of animal food
- Treating and disposing of waste so that it will not contaminate exposed animal food



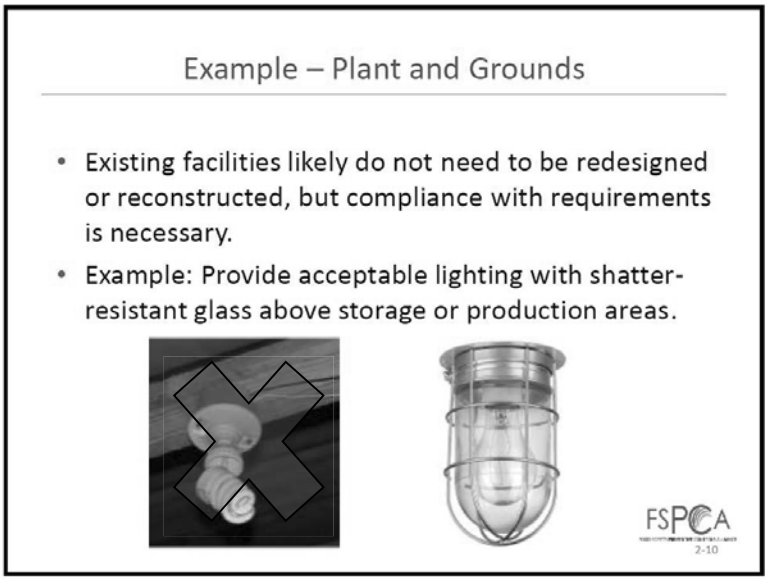
'Adequate' is defined in the rule as: *that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.*

The adequacy of facility design, such as space between equipment or ventilation, is dependent upon the facility and type of animal food being manufactured, processed, packed, or stored. Ultimately, the definition of adequate is what is appropriate to ensure animal food is safe.

Slide 9

The second set of requirements relates to the design and construction of the facility. Specifically, it must be feasible to clean, perform maintenance activities, and control pests in order to reduce the potential for contamination of animal food, contact surfaces, and packaging materials. The facility must:

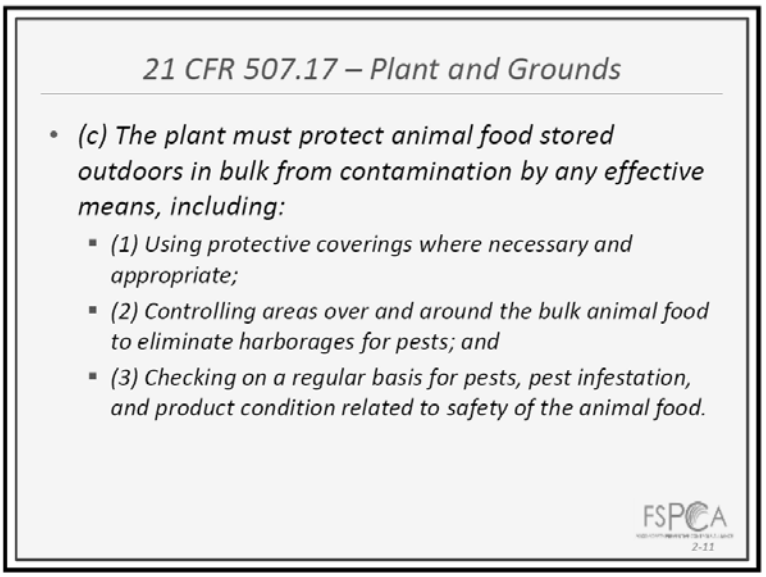
- Provide adequate space throughout the facility for employees to perform their duties related to cleaning and maintenance of equipment
- Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination
- Provide adequate ventilation where appropriate to minimize vapors and fumes that may contaminate animal food
- Provide adequate lighting in hand-washing areas and bathrooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned
- Provide shatter-resistant light bulbs, fixtures, skylights, or other glass items when they are suspended over exposed animal food in any step of the process



Slide 10

It is important to note that the preamble of the *Preventive Controls for Animal Food* rule states that existing facilities likely do not need to be redesigned or reconstructed to meet the CGMP requirements. Maintenance, repair, retrofitting, or other changes to the existing facility, equipment, or facility procedures may be used to meet the requirements. For example, when possible, fixtures, ducts, and pipes should not be located over areas where animal food or animal food-contact surfaces are located. In an existing facility, condensation can be controlled by using drip pans to divert water away from animal food, or by installing pipe insulation to prevent sweating.

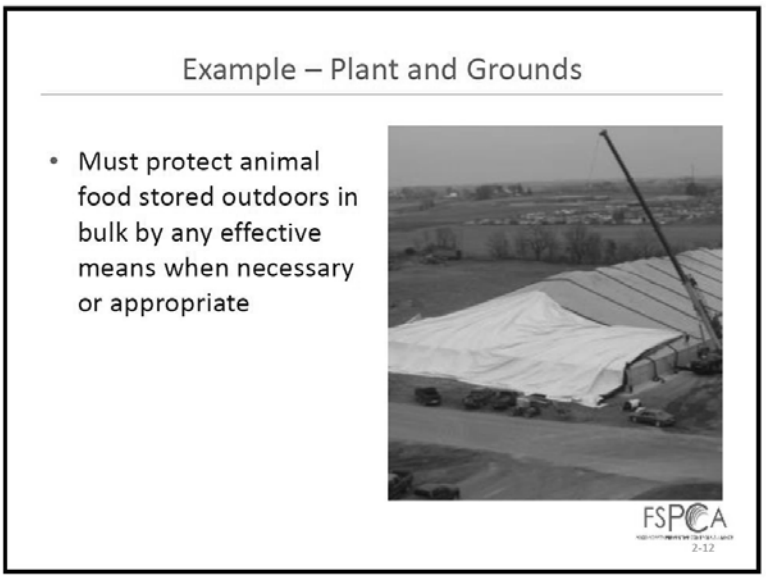
At a given facility, complying with the CGMP requirements might mean implementing an outdoor maintenance program that provides specific policies related to the proper conditions of the grounds. Inside the facility, it may be that space and ventilation are already addressed because of their impact on facility operations. To address the potential for glass breakage, a facility may need to evaluate its lighting and other glass fixtures that are in place over exposed animal food to ensure the use of shatter-resistant glass or other adequate protection. In areas where the lighting is not adequate for employees to perform their duties, additional lighting should be added.



Slide 11

The third set of requirements relates to protecting any animal food stored outdoors in bulk. The facility may use any effective means to protect against contamination, including:

- Using protective coverings
- Controlling areas over and around the bulk animal food to eliminate harborages for pests
- Checking the animal food on a regular basis for pest activity and any signs of poor product conditions that could be related to the safety of the animal food

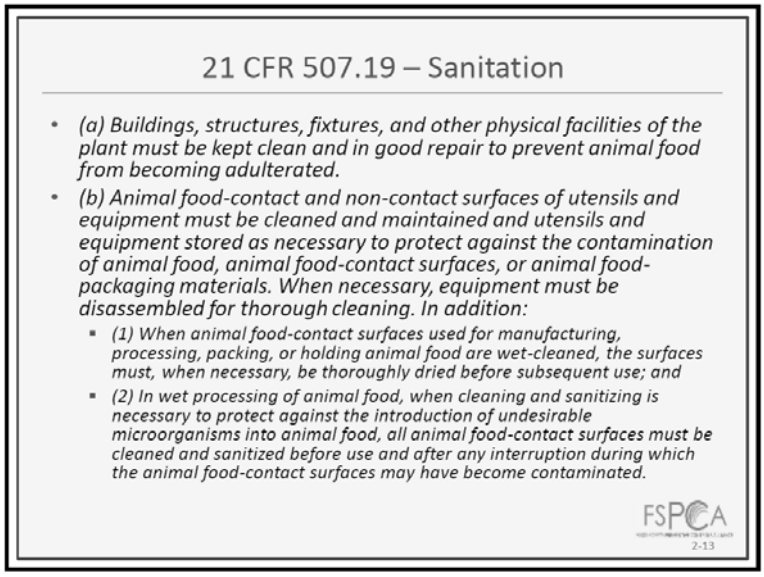


The preamble of the *Preventive Controls for Animal Food Rule* includes additional language regarding when it is appropriate to protect animal food stored outdoors, such as ground piles of grain. Establishments that are exempt from the rule, such as those solely engaged in the holding and transporting of raw agricultural commodities, are exempt from this requirement and the rest of the CGMPs. Not all situations will require protective coverings. The rule stipulates protective coverings must be used ***where necessary and appropriate*** to ensure animal food safety is maintained.

Regardless of whether a facility is subject to the CGMP requirements, they are still responsible for producing safe animal food that is not adulterated.

Slide 12

In some parts of the country, during harvest time, large quantities of grain may be stored in piles until the grain can be moved by rail to a more permanent storage location. Depending upon the length of storage and conditions, the outdoor pile may be protected by various means. For example, it may be necessary and appropriate to cover animal food with a tarp or other similar material to protect against contamination from outdoor elements, such as rain or wind-blown debris, or pests; for example, by bird or rodent droppings or nesting materials. Supervisory personnel would ultimately be responsible for determining the necessary and appropriate precautions needed to address potential contamination from the environment and/or pests.

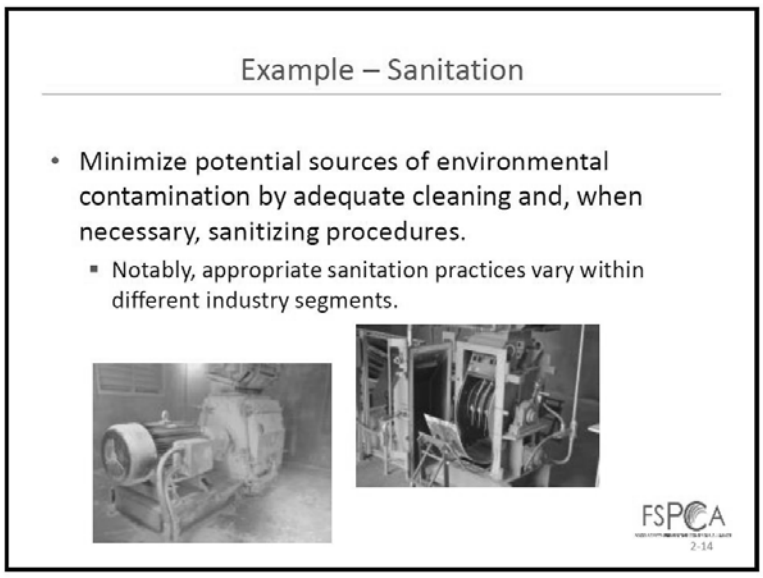


Slide 13

21 CFR 507.19 addresses the CGMP requirements related to sanitation. The primary goal of the CGMP requirements in this section is to describe the activities necessary to ensure that the physical facilities of the plant are kept clean and in good repair to prevent animal food from becoming adulterated.

Both contact and non-contact surfaces of utensils and equipment must be cleaned and maintained as necessary. Also, utensils and equipment must be properly stored to protect against the contamination of animal food, contact surfaces, or packaging materials. When necessary, equipment must be disassembled for thorough cleaning.

In situations where wet-cleaning is appropriate, surfaces must, when necessary, be thoroughly dried before subsequent use. When cleaning and sanitizing is necessary to protect against contamination by undesirable microorganisms, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

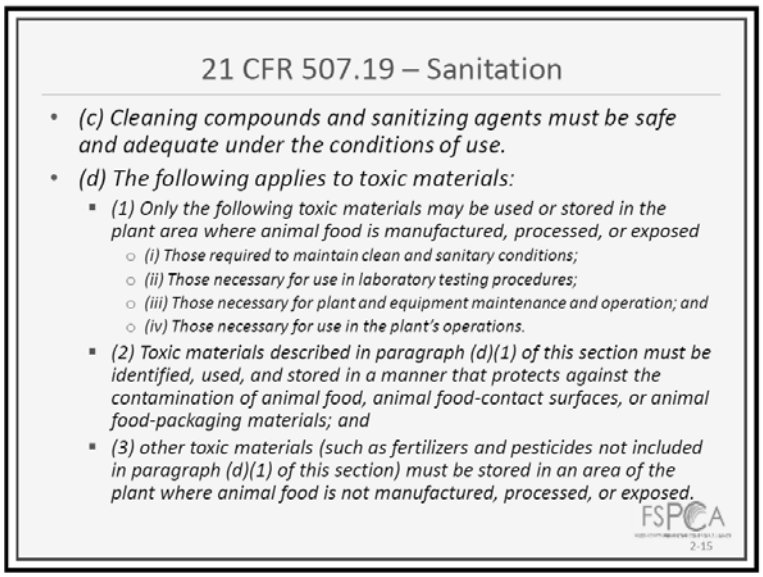


Slide 14

For many facilities, sanitation compliance will be tied to basic housekeeping practices. Take, for example, the level of acceptable cleanliness in the pictures in the slide. The picture on the left shows a hammermill in use. The picture on the right shows a brand new hammermill before it has ever been used. Even with a dust collection system, hammermills generate dust during use. While there is dust on the equipment and in the grinding room pictured on the left, it is clear that housekeeping is used to minimize buildup over a long period of time. There is no evidence of pests or buildup causing a potential hazard.

It is important to note that the level of acceptable sanitation may differ between animal food manufacturing facilities based on the type of food they produce and any associated hazards. For example, in some animal food facilities where wet cleaning is performed, equipment may be disassembled and sanitized as necessary.

As with other CGMP sections, the management of the establishment is responsible to ensure the measures taken to comply with the sanitation requirements will protect against the contamination of the animal food.



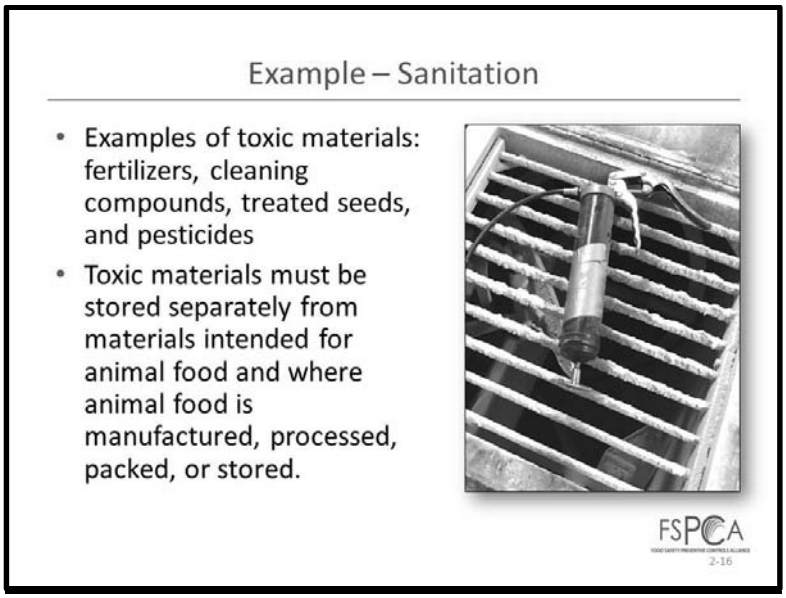
Slide 15

All cleaning compounds and sanitizing agents must be safe and adequate for their intended use.

Only certain toxic materials may be used or stored in areas of the facility where animal food is manufactured, processed, or exposed. These include:

- Those required to maintain clean and sanitary conditions (e.g. cleaning compounds)
- Those used in laboratory testing procedures (e.g. reagent chemicals)
- Those necessary for facility and equipment maintenance and operation (e.g. greases and oils)
- Those necessary for use in facility operations (e.g. sweeping compounds)

Any such toxic materials must be identified, used, and stored in a manner that protects against the contamination of animal food, contact surfaces, or packaging materials. All other toxic materials not specifically addressed must be stored away from any areas where animal food is manufactured, processed, or exposed.



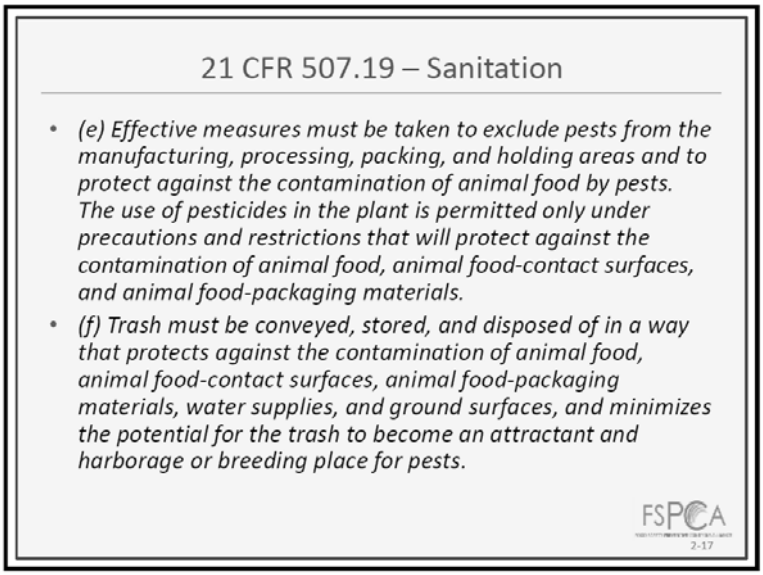
This picture is of a non-food-grade grease gun laying on top of a hand-addition port on the top of a mixer. Non-food-grade grease could be a toxic contaminant in animal food. Its use is acceptable because it is necessary for facility and equipment maintenance and operation. However, it must be stored properly and not come in contact with animal food, animal food-contact surfaces, or animal food-packaging material.

Instead of storing the toxic chemical as shown in the picture, it should be stored outside the manufacturing area. Alternatively, food-grade grease could be substituted to eliminate the need for the toxic material. Food-grade grease would be important to use on any bearings that come in contact with animal food, such as in a pellet mill roll assembly.

Slide 16

There are many animal food manufacturing facilities that store and sell toxic materials such as fertilizers, cleaning compounds, treated seeds, and pesticides. While this is an acceptable activity, those materials must be stored in an area of the facility where animal food is not manufactured, processed, or exposed.

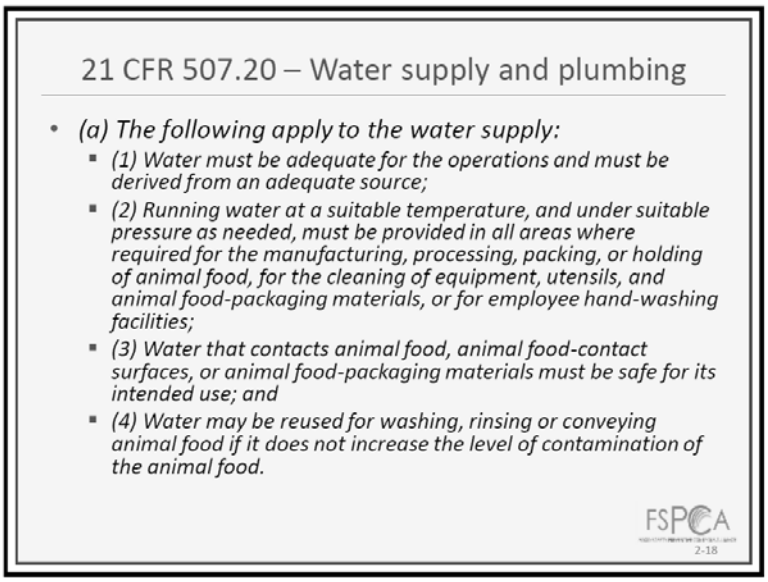
In the preamble of the rule, FDA states that it expects this requirement to result in these toxic materials being separated from animal food either by sufficient space or a sufficient physical barrier such that they are not able to contaminate the animal food. As a good practice, these toxic materials should be stored separately from materials that are intended for animal food, such as ingredients, finished animal food, or packaging materials.



Slide 17

Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas of the facility. While pesticides may be used within the facility, according to these requirements, precautions must be taken to protect against the contamination of animal food, contact surfaces, and packaging materials.

Trash must be conveyed, stored, and disposed of in a way that will not contaminate animal food, contact surfaces, packaging materials, water supplies, or ground surfaces. Further, trash must be handled in such a way that minimizes the potential for it attract or harbor pests.

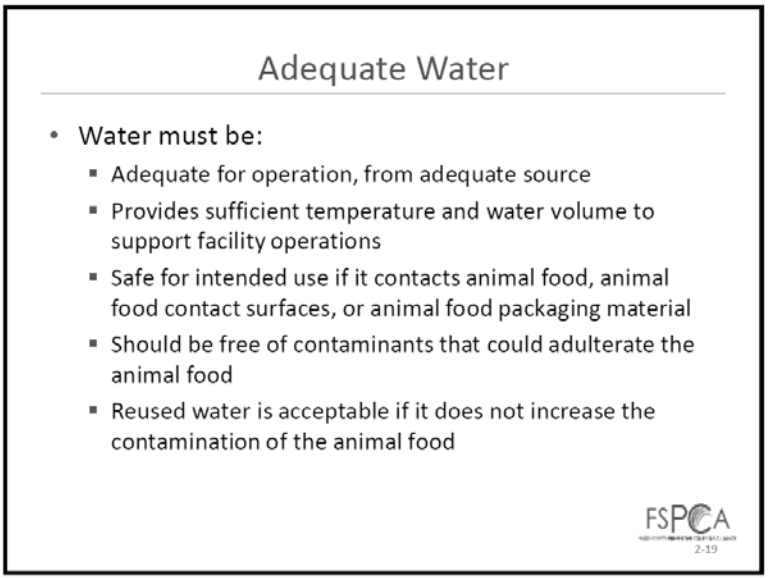


Slide 18

21 CFR 507.20 describes the requirements for water supply and plumbing. Requirements relate specifically to the water supply, plumbing, waste disposal, and toilet and hand-washing facilities. It is important to note that not all animal food facilities may use water for manufacturing, and therefore some of the requirements related to water used for operations may not be applicable.

The following requirements apply to the water supply:

- Water must be adequate for the operations and come from an adequate source
- Running water at a suitable temperature and pressure must be provided as required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities
- Water that contacts animal food, contact surfaces, or packaging materials must be safe for its intended use
- Water may be reused for washing, rinsing or conveying animal food if it does not increase the level of contamination



As an example, for facilities using city water, there are often municipal water reports available that may provide the necessary information to ensure the water source is adequate. Conversely, facilities using well water may find well certification records at the county water department that declare water adequacy.

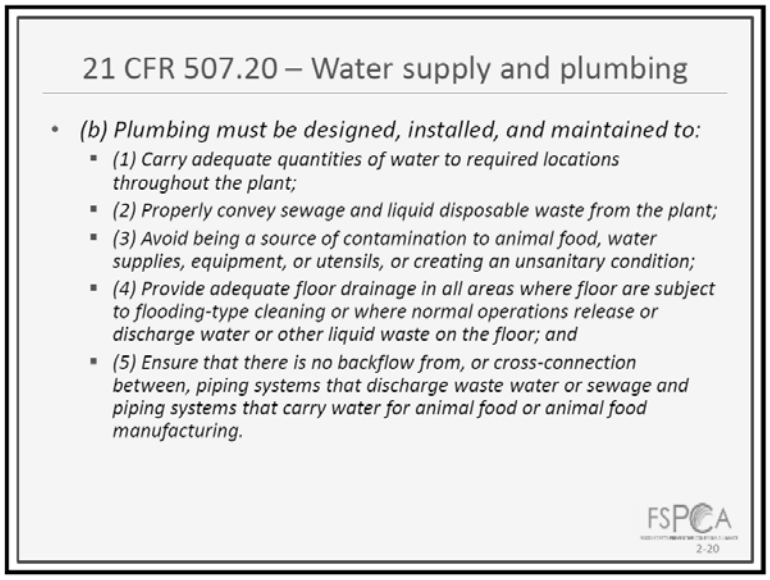
Slide 19

Water used by the facility must be adequate for the operations and derived from an adequate source. Adequate is a defined term in the rule, and in this sense, the water supply must be sufficient for its intended purpose, in keeping with good public health practice. The water supply must provide sufficient water volume to support the facility operations (e.g., manufacturing, processing, and cleaning). Water treatment methods may be used to improve the water quality or to remove contaminants.

The most impactful of the water supply and plumbing requirements are likely to be those related to the use of water in the manufacturing of an animal food. Water may be added to foods during processing, such as during the steam conditioning process prior to pelleting or extrusion. Also, many facilities may utilize water to clean utensils, such as scoops. In these cases, facilities could maintain records of water safety, either from a water treatment department or, in the case of facilities utilizing well water, through periodic testing of water quality. However, the type or frequency of water testing is not specified in the regulations.

Depending on the intended use, water may need to meet certain standards, or be free of certain chemical (including radiological) or biological contaminants. The water source cannot introduce contaminants that could adulterate the animal food. The water source should be in compliance with any other applicable regulations.

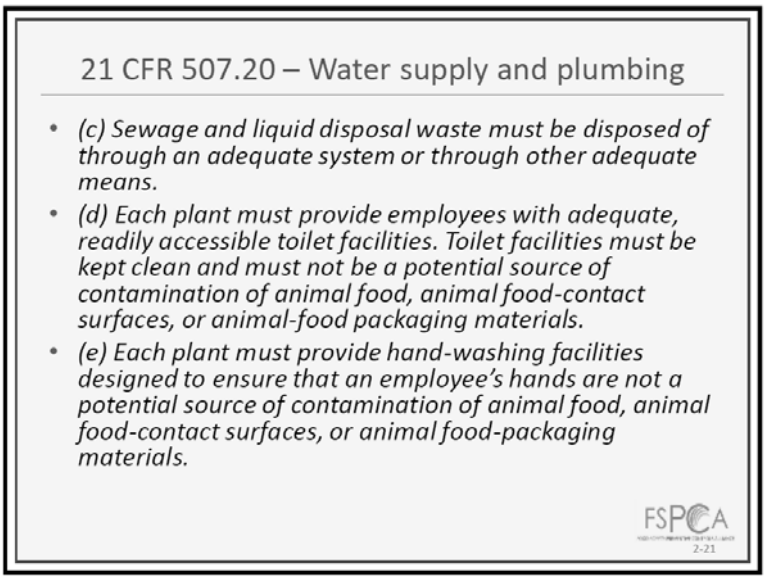
The CGMPs do not require testing for water safety; however, testing may be one way to determine whether the water source is adequate and safe for its intended use. Test reports may be one way for to demonstrate that the facility determined the water source is adequate and safe for its intended use.



Slide 20

Facility plumbing must be designed, installed, and maintained to:

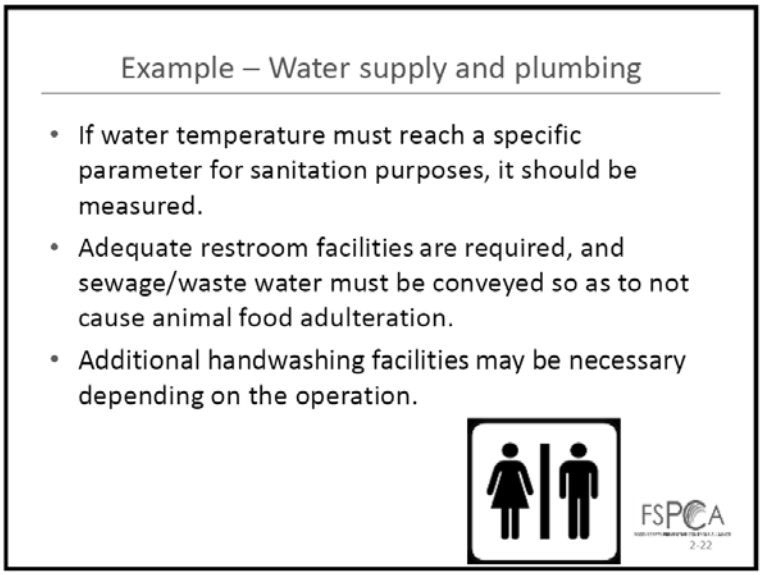
- Carry adequate quantities of water to required locations throughout the facility
- Properly convey sewage and liquid waste
- Avoid being a source of contamination or creating an unsanitary condition
- Provide adequate floor drainage for cleaning or where normal operations release or discharge water or other liquid waste
- Ensure that there is no potential for cross contamination between waste water or sewage and water used in animal food manufacturing



Slide 21

Sewage and liquid waste must be adequately disposed of.

Each facility must provide employees with adequate and readily accessible toilet facilities. Some facilities may not have toilet facilities physically in the facility, which is acceptable as long as there are toilet facilities nearby and readily accessible. In some instances, the facility may need to arrange to share common toilet facilities in a shared building, or with a nearby building. For seasonal operations or operations without a building, arrangements for access to toilet facilities may need to be made with a nearby building or for the use of portable toilet facilities. These facilities must be kept clean so as not to become a potential source of contamination. Similarly, a facility must also provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination.



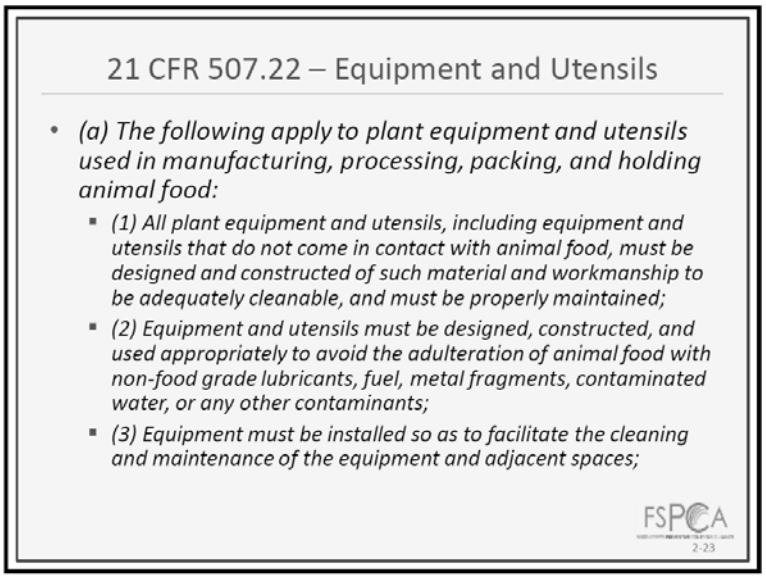
Examples of the appropriate temperature for handwashing is described in the FDA Employee Health and Personal Hygiene Handbook, which may be found at http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm113827.htm.

This reference is intended for employees of human food facilities or retail food facilities, but may contain information that can be helpful for certain types of animal food manufacturing, processing, packing, or holding. Water temperature may be more important in facilities where handwashing is used to prevent the spread of undesirable microorganisms.

Slide 22

In some facilities, hot water is used for sanitation of equipment. In this case, a facility may choose to measure the temperature of the water in accordance with a written policy. Records might be generated if considered important by the facility, but such records would not be required as there is no recordkeeping associated with CGMP requirements.

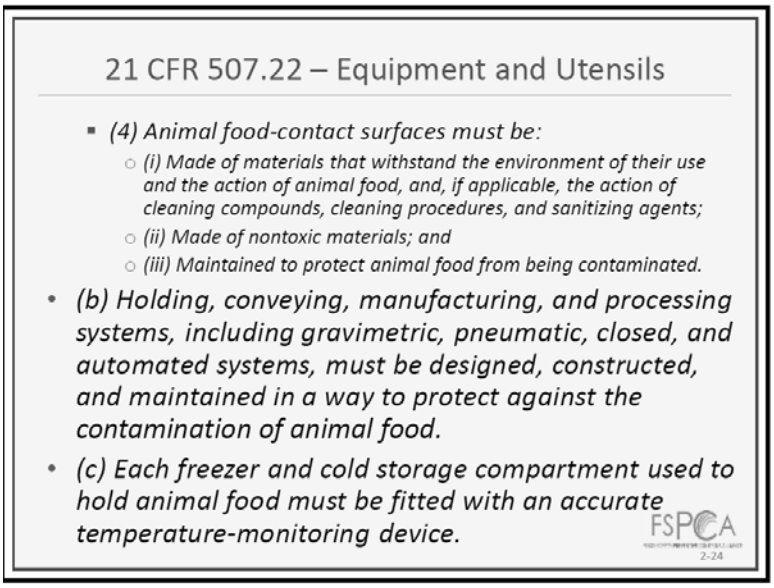
Hand-washing facilities should be provided as part of the toilet facilities. Additional hand-washing facilities may be needed throughout the facility, especially if microbiological contamination is a food safety concern for the type of animal food being produced. If this is the case, hand-washing facilities should be conveniently located near operations where employees may be switching between non-food-contact surfaces and food-contact surfaces, or switching between handling raw materials or ingredients and finished animal food. For seasonal operations or operations without a building, arrangements may need to be made for access to gravity fed hand-washing facilities. Hand-washing facilities should include running water, soap, and a method to dry hands after washing. There may be some situations where hand-washing facilities are not necessary for the production of safe animal food. The use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances.



Slide 23

21 CFR 507.22 describes the CGMP requirements for equipment and utensils. All equipment and utensils used in the manufacturing, processing, packing, and holding of animal food must be:

- Designed and constructed to be adequately cleaned (this includes equipment and utensils that do not come into direct contact with animal food)
- Properly maintained
- Designed, constructed, and used in such a way to avoid the adulteration of animal food with any contaminants
- Installed in such a way to allow for cleaning and maintenance of both the equipment and the adjacent spaces.

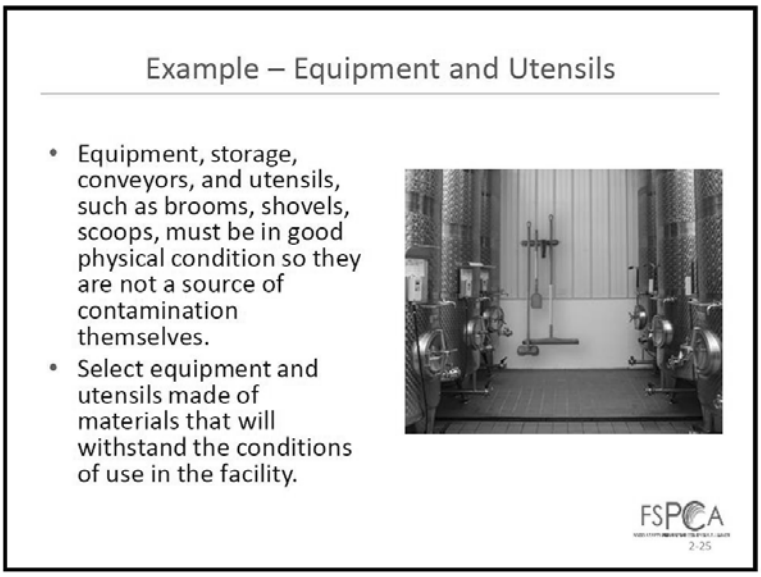


Slide 24

Animal food contact surfaces must be:

- Made of materials that can withstand the environment, animal food, and any cleaning compounds and procedures
- Made of nontoxic materials
- Maintained to protect against contamination

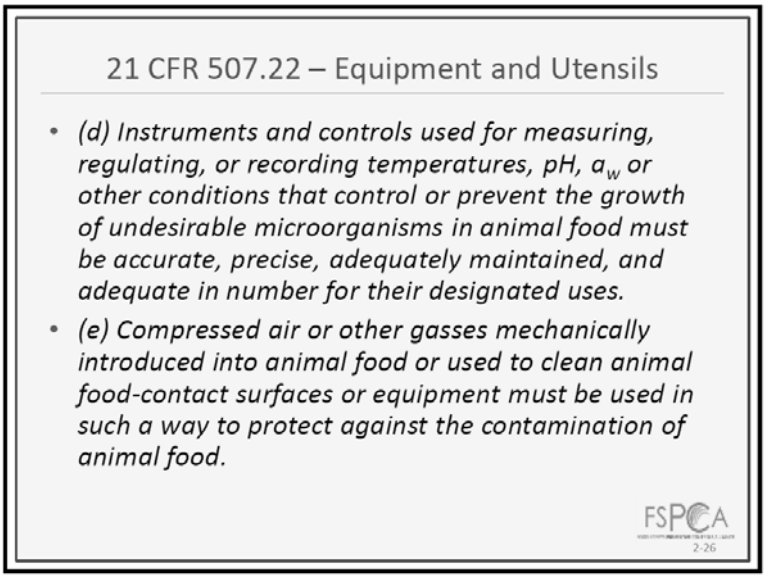
All systems, including holding, conveying, and manufacturing and processing systems, must be designed, constructed, and maintained to protect against contamination of animal food. Such systems could include components such as ingredient storage bins, bucket elevators, and thermal processing equipment. For applicable facilities, each freezer or cold storage holding animal food must have a method to accurately monitor the temperature. The monitoring instrument could be as simple as an individual thermometer, or as sophisticated as an automated system that continuously monitors the temperature and initiates an alarm when an unsafe condition exists.



Slide 25

Equipment and utensils should be maintained so that they do not become a source of contamination. This includes keeping items in good physical condition so that broken or corroded pieces do not fall off and contaminate the animal food. It also includes keeping items clean, especially those utensils and pieces of equipment that may be used in multiple areas and/or with multiple types of animal foods. A facility may consider labeling any specific use utensils to reduce cross contamination concerns.

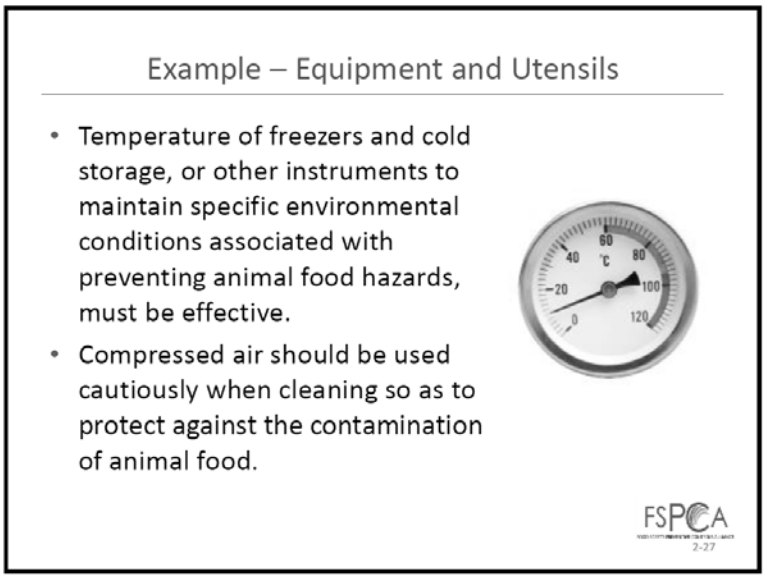
It is important to select equipment and utensils that are constructed of materials that will not easily deteriorate under the conditions of use. For example, equipment or utensils used in a wet environment should be constructed of suitable materials that will not corrode or deteriorate under wet conditions.



Slide 26

Any instruments used for measuring, regulating, or recording conditions (such as pH or water activity, a_w) that control or prevent the growth of undesirable microorganisms must be accurate, precise, adequately maintained, and adequate in number for their intended use.

Any compressed air or other gasses employed in the manufacture of an animal food or for cleaning purposes must be used in a way that protects against contamination of animal food.

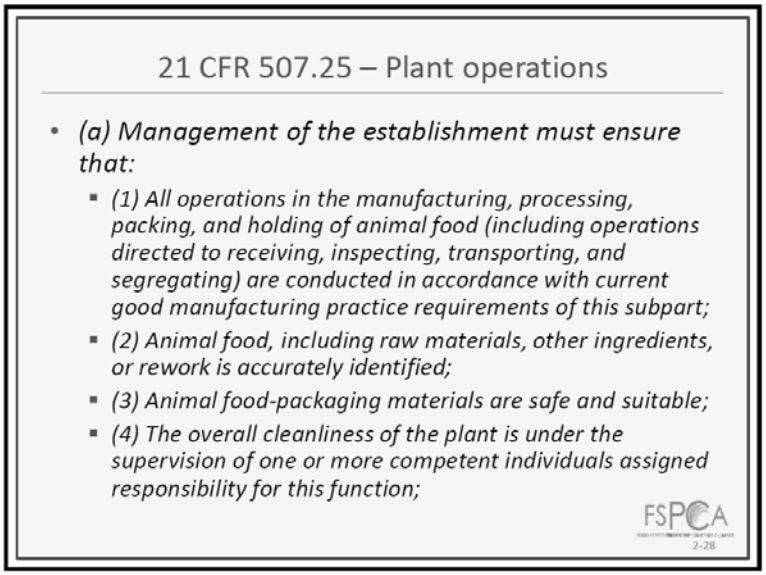


Compressed air can be used, but only in a way that protects against contamination of animal food. For example, some facilities concerned with compressed air introducing biological hazards may filter their compressed air and/or test it periodically for safety. In other instances, compressed air used for cleaning a hazard, such as aflatoxin-contaminated corn dust, must be used in a way so that the dust does not contaminate animal food.

Slide 27

In any situation where a device, such as a thermometer or pH meter, is being used to monitor and maintain conditions related to animal food safety, it is very important that the devices are accurate, precise, and adequately maintained. A poorly functioning device is likely to do more harm than good by providing inaccurate information. It is also important that the facility has enough devices for their designated uses. For example, if a facility has two production lines that need to reach certain temperatures to control the growth of undesirable microorganisms, the facility should have a temperature-measuring device for each production line.

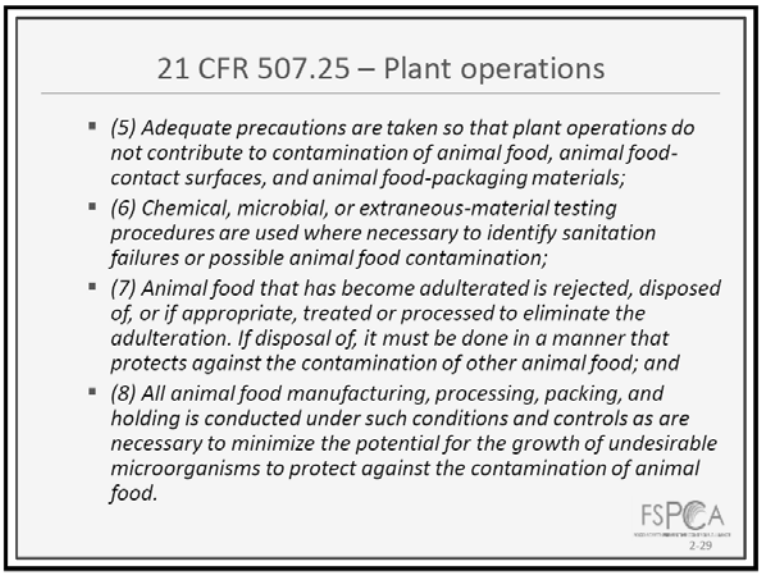
Compressed air can be a popular way to clean large areas, especially when some surfaces are hard to reach. In addition to following safety protocols related to dust-explosion hazards, compressed air must be used in a manner that protects against the contamination of animal food. If contamination cannot be avoided, other methods of cleaning, such as sweeping or vacuuming, must be used.



Slide 28

21 CFR 507.25 introduces the CGMP requirements related to general facility operations. The first part of the requirements focuses on the responsibilities of management (21 CFR 507.25(a)). These responsibilities include ensuring that:

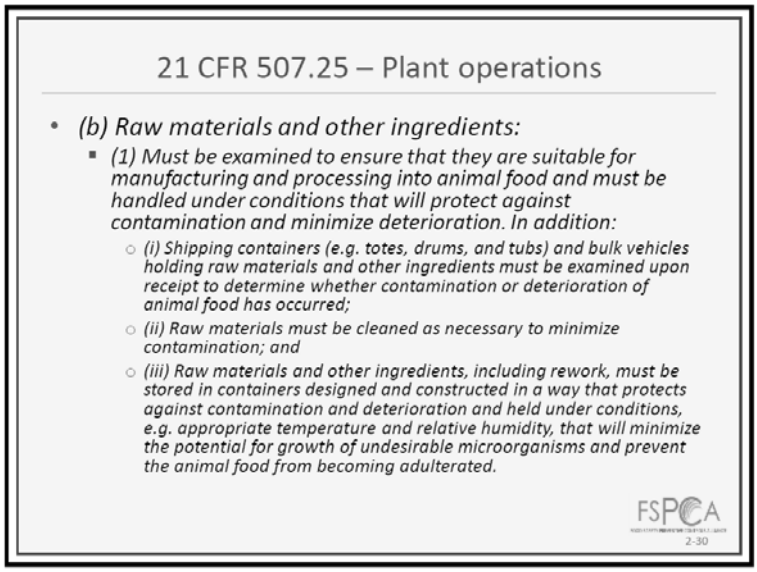
- All establishment operations are conducted in accordance with CGMP requirements
- All animal food, which includes ingredients and raw materials, is accurately identified
- Packaging materials are safe and suitable for the intended use
- Facility cleanliness is under proper and assigned supervision



Slide 29

Continuing from the previous slide, management is also responsible for ensuring that:

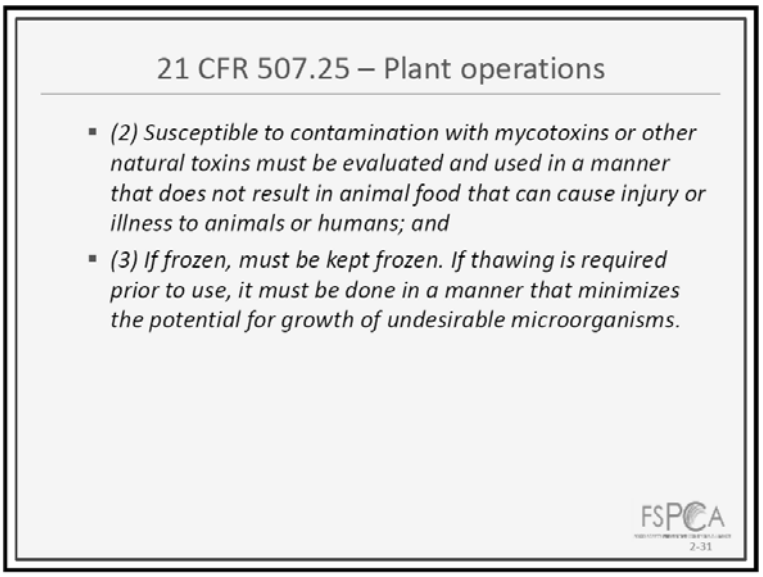
- Adequate precautions are taken to prevent facility operations from contributing to contamination of animal food, contact surfaces, or packaging materials.
- Testing procedures are used as necessary to identify sanitation failures or animal food contamination
- Any adulterated animal food is either disposed of in such a way that does not contaminate other animal food, or is appropriately treated or processed to eliminate the adulteration.
- Operations are conducted under conditions and controls deemed necessary to protect against the contamination of animal foods by undesirable microorganisms



Slide 30

The second part of 21 CFR 507.25 – Plant Operations requirements focuses on raw materials and other ingredients (21 CFR 507.25(b)). All raw materials and other ingredients must be examined to ensure they are suitable for the animal food being manufactured. Materials must also be handled in such a way to protect against contamination and minimize deterioration.

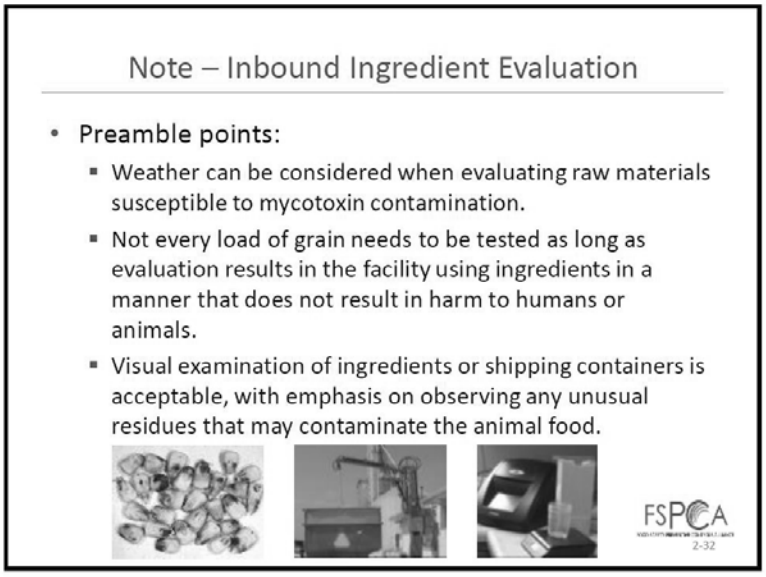
- All containers and bulk vehicles holding incoming raw materials and ingredients must be examined at receiving to determine if any contamination or deterioration has obviously occurred.
- As necessary, raw materials must be cleaned to minimize contamination.
- All raw materials and rework must be stored in such a way that protects against contamination, deterioration, and potential adulteration due to the growth of undesirable microorganisms.



Slide 31

Any raw materials susceptible to natural toxins, most commonly mycotoxins, must be evaluated and used in such a way that both human and animal health is protected.

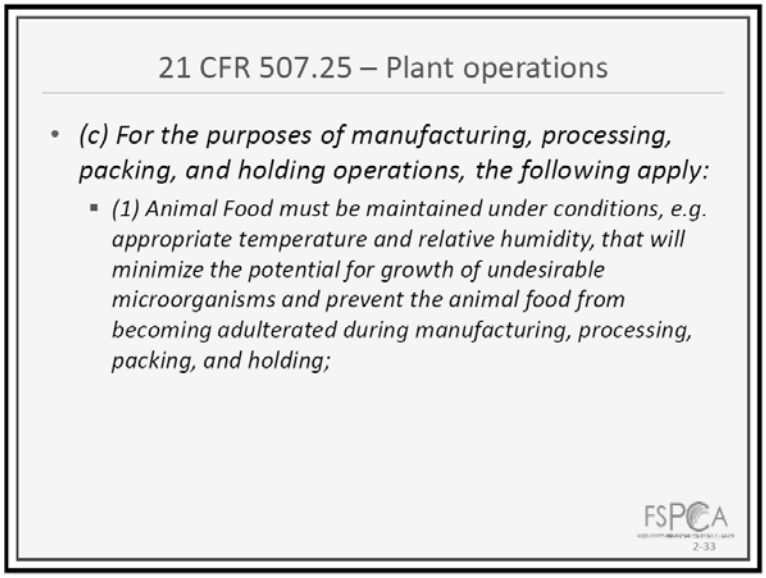
For any raw material that is frozen, it must remain frozen until use, at which time any thawing must be done in a way that minimizes the potential for growth of undesirable microorganisms.



Slide 32

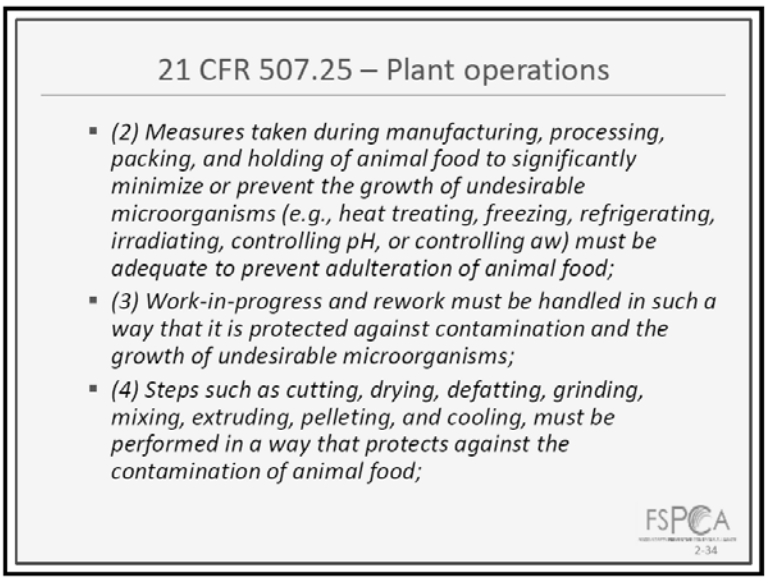
It is worth noting here some specific points raised by the preamble to the *Preventive Controls for Animal Food* rule.

- When considering the need to evaluate incoming raw materials that are susceptible to mycotoxins, an establishment can take into consideration current weather-related information. For example, if conditions were not favorable for mycotoxins, less frequent observation may be warranted.
- Using mycotoxins as an example, it is not required that every load of grain be tested; rather, the requirement is that some method be established to ensure that the facility uses potentially affected ingredients in a manner that protects both human and animal health.
- Visual examination may be a perfectly acceptable method of examining both ingredients and containers, so long as there is an emphasis on looking for unusual characteristics, properties, or residues that may indicate contamination. For example, gnawed packaging may indicate that the ingredient has been potentially contaminated by rodents



Slide 33

The last section of 21 CFR 507.25(c) is more general in nature and lists requirements for manufacturing, processing, packing, and holding. During manufacturing, processing, packing and holding, all animal food must be maintained under conditions that minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated. There are eight sub-bullets under 507.25(c) which will be covered in the next three slides.

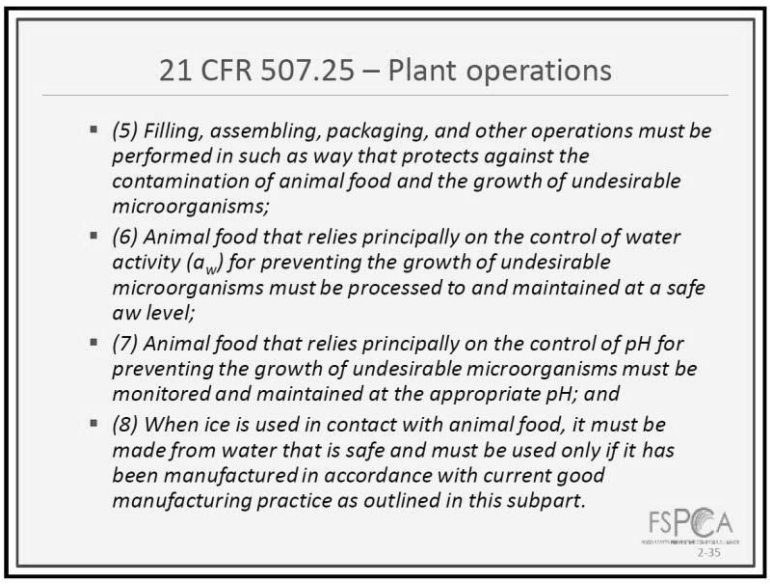


Slide 34

Specific measures may be taken during the manufacturing, processing, packing and holding of animal food to minimize or prevent the growth of undesirable microorganisms. These measures might include heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling water activity. If any of these methods are used for the specific purpose of addressing the growth of undesirable microorganisms, they must be adequate to prevent adulteration.

During the manufacturing process, any work-in-progress or rework must be handled so as to protect against contamination and the growth of undesirable microorganisms.

All processing steps must be performed in a way that protects against contamination.

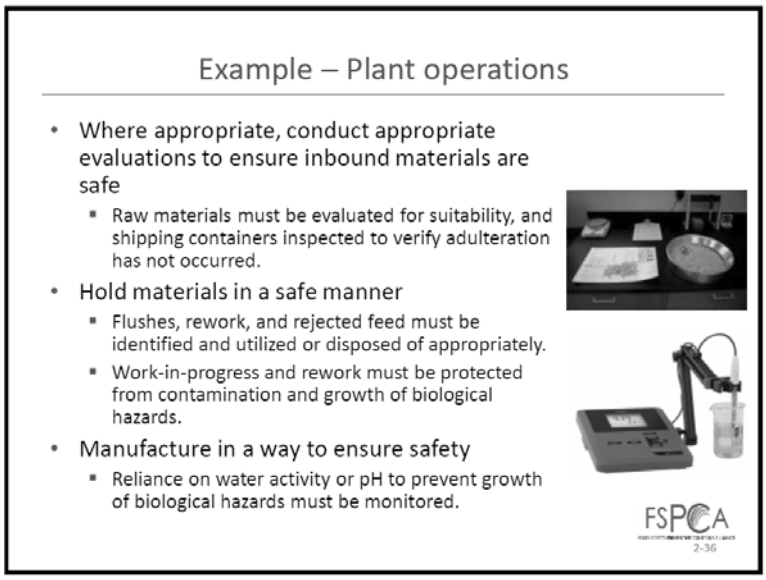


Slide 35

All filling and packaging operations must be performed in a way that protects against contamination and the growth of undesirable microorganisms.

Animal food that relies on either water activity and/or pH to prevent the growth of undesirable microorganisms must be processed, monitored, and maintained at safe and appropriate levels.

If ice is to be used in manufacturing, processing, packing, or holding, and it will come into contact with animal food, it must be made from a safe source of water in accordance with CGMP requirements.



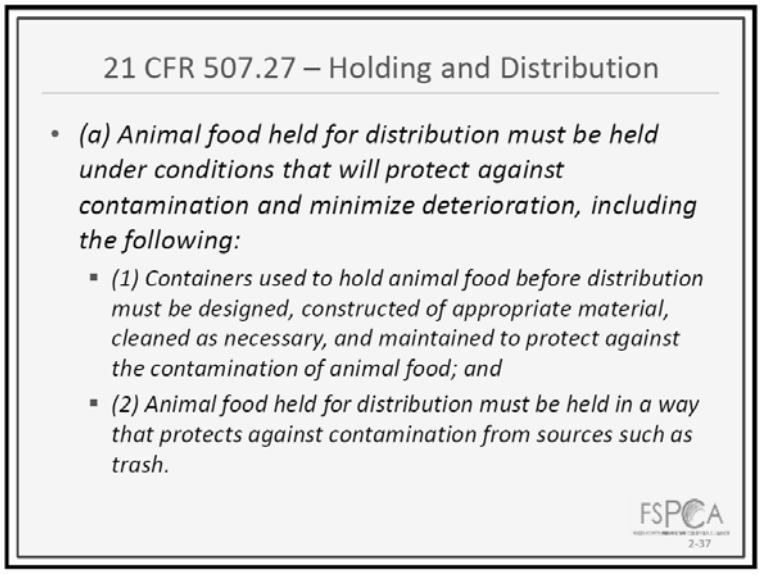
Slide 36

In general terms, the CGMP requirements related to facility operations require an establishment to evaluate inbound materials to make sure they are safe. Evaluation may include:

- Reviewing specifications, guarantees, or other associated information received by the facility
- Performing a visual check of the animal food or its packaging
- Performing relevant sampling and testing; and/or
- Checking incoming temperatures for refrigerated or frozen ingredients

The CGMPs also requires that a facility hold all the materials in safe manner. All materials, including those such as flushes, rework, and rejected food must be accurately identified. Identification may include labeling, computer systems, paper records, chalkboards, and other methods. Note that in the preamble of the rule, FDA states bulk silos and bins are not required to be placarded, because this is impractical and not a common industry practice. Materials in bulk bins and silos may be identified by any effective means. Facility personnel should be able to accurately identify animal food, including raw materials, other ingredients, rework, or finished animal food within the facility so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food.

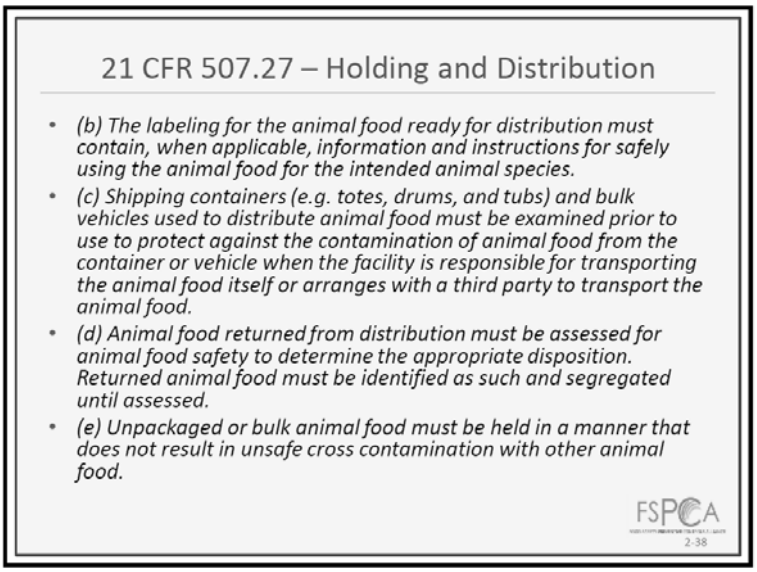
Finally, the facility must manufacture animal foods using processes that will not lead to contamination or adulteration.



Slide 37

21 CFR 507.27 provides the CGMP requirements for holding and distribution. All animal food must be held under conditions that will protect against contamination and deterioration. These conditions and practices include:

- Containers being designed, appropriately constructed, cleaned as necessary, and maintained to protect against contamination
- Holding animal food for distribution so that it does not become contaminated by sources such as trash



There are additional responsibilities for facilities that load and/or transport animal food that are part of the *Sanitary Transportation* rule of FSMA.

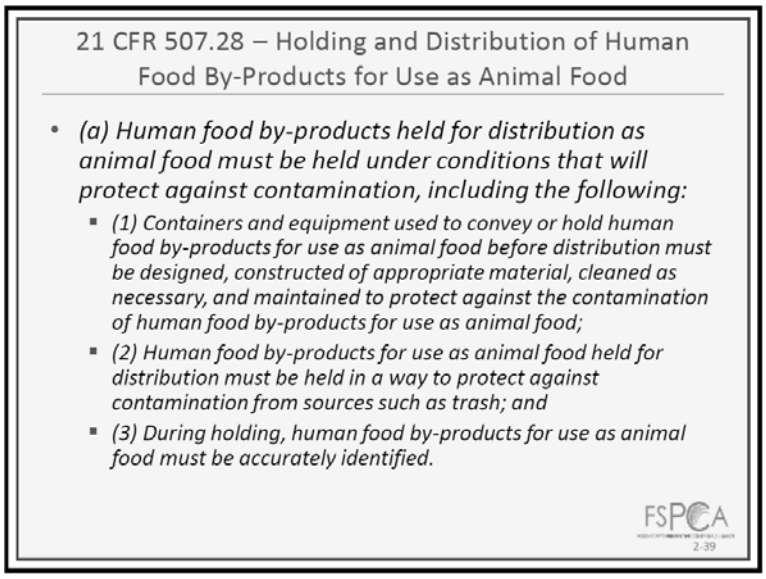
Slide 38

Animal food labeling must contain, when applicable, information and instructions related to the safe use of the animal food for the intended animal species.

All shipping containers and bulk vehicles must be examined prior to use when the facility is responsible for transport or arranges transport with a third party.

Any animal food returned from distribution must be identified, segregated, and evaluated for safety to determine the appropriate disposition.

Any unpackaged or bulk animal food must be held in such a way that does not result in any unsafe cross contamination with other animal foods.

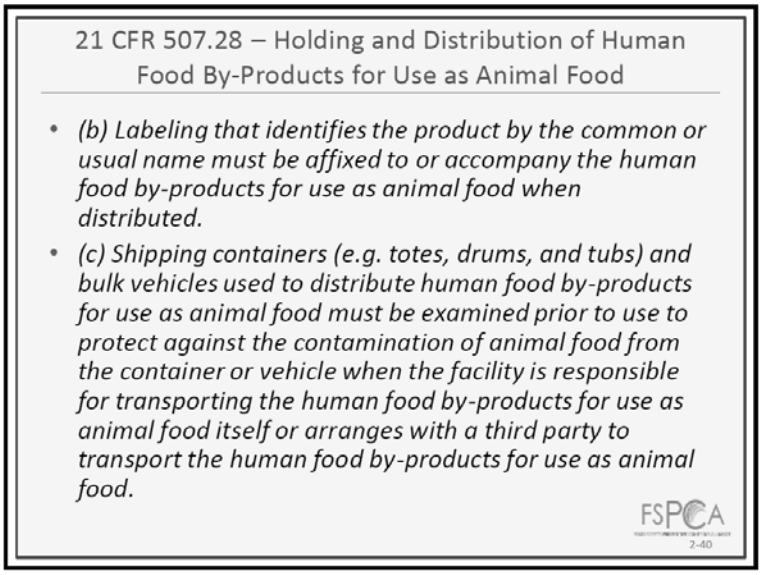


Slide 39

21 CFR 507.28 provides requirements for holding and distribution of human food by-products for use as animal food. This provision only applies to human food facilities that meet the conditions in 21 CFR 507.12. These facilities only have to follow these holding and distribution requirements for their human food by-products for use as animal food. These requirements are very similar to the previous holding and distribution requirements for all other animal food facilities outlined in 21 CFR 507.27. In this slide, only the last bullet is a significant addition, and states that during holding, human food by-products for use as animal food must be accurately identified. Regardless of how the human food by-product for use as animal food is labeled, the intent is to distinguish animal food from trash or material for other uses.

For animal food, the requirement that the animal food be accurately identified is in 21 CFR 507.25 Plant operations. As a result, there is no need for a specific holding and distribution requirement in 21 CFR 507.27 that animal food be identified. Because the human food by-products for use as animal food are only subject to 21 CFR 507.28 and not 21 CFR 507.25, there is a specific requirement in 21 CFR 507.28 that the human food by-products for animal food be accurately identified while held for distribution. The accurate identification of animal food, including human food by-products for animal food, is important so that the animal food is not mistaken for something else which could lead to an employee accidentally contaminating the animal food being held for distribution, or accidentally contaminating other animal food because of improper commingling or substitution.

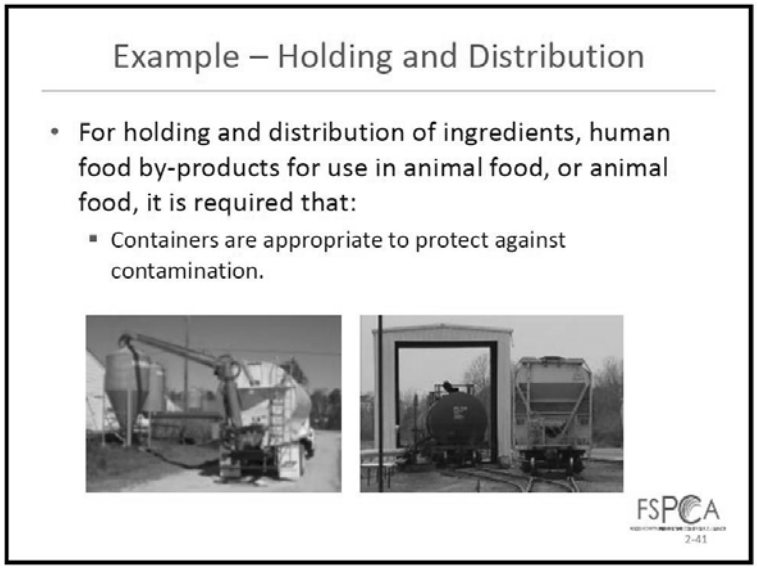
How this identification occurs can be flexible. For example, some facilities may choose to label individual drums with the specifications of what is in each container and its intended use. Others may label wheelbarrows as 'animal food' to distinguish



'Labeling' may mean the physical container is labeled or that the bin where the animal food is stored is labeled on the computer screen in an electronic system or on a whiteboard. The labeling component is flexible, but requires that human food by-product intended for use as animal food is labeled to ensure its safe use.

Slide 40

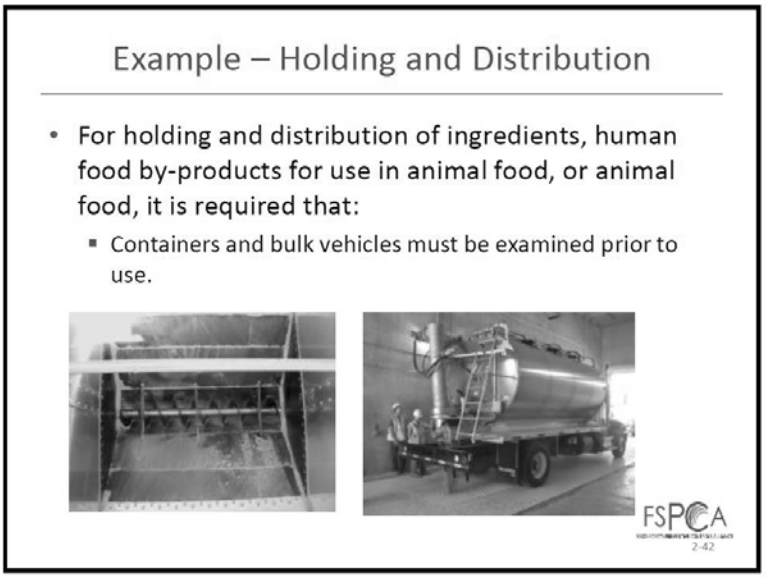
In this slide, the only difference of significance from the holding and distribution requirements in 21 CFR 507.27 is that the labeling for human food by-products is required to identify the product by the common or usual name.



Slide 41

The general CGMP requirements for the holding and distribution of ingredients, human food by-products, and animal food are that:

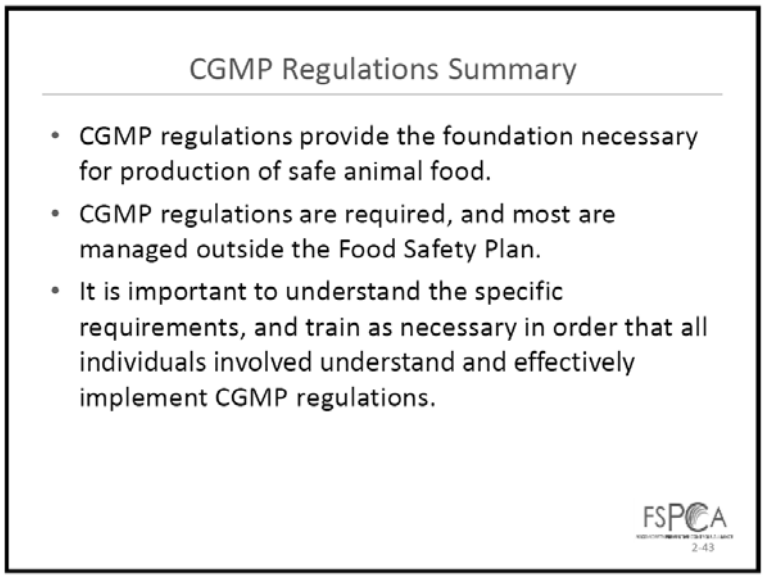
- Containers and bulk vehicles are appropriate to protect against contamination the animal food, such as by microbial growth or physical contaminants. They must be designed, constructed of appropriate material, cleaned as necessary, and properly maintained.
- Facilities may use different container cleaning methods and frequency of cleaning, repair, or replacement depending on the animal food held and the facility's holding practices.
- Facilities should consider the type of containers, the amount and type of animal food, how often the containers are reused, whether the containers are transferred to other sites (other facilities or farms), as well as other factors in deciding what practices will be sufficient to protect the animal food from contamination and deterioration



Slide 42

Containers and bulk vehicles must be examined prior to use when the facility is the shipper. This examination could include looking at the shipping container or vehicle to observe whether there are any residues in it that may contaminate the ingredients, human food by-product for use as animal food, or animal food. When a visual examination is not practical, the facility should know what the shipping container or vehicle had previously been used for and because of that, whether the container needs to be cleaned prior to use to protect the animal food from contamination. This does not mean that the shipping container must be cleaned prior to each use in all situations.

When the facility is the shipper they are responsible for examining containers prior to use. However when the customer arranges the shipping, examination is not required by the facility. However, the *Sanitary Transportation of Human and Animal Food* rule requires facilities that load animal food to determine that transportation equipment, such as trucks or railcars, must be in appropriate sanitary condition, regardless if the loading facility arranged for the conveyance or not.



The activities emphasized by the Current Good Manufacturing Practice requirements are those that can be observed within a facility and do not require specific documentation. CGMP requirements establish baseline standards for producing safe animal food and support the development and effective implementation of a food safety plan, where applicable.

The CGMP requirements do not include recordkeeping requirements. However, in some instances a facility may want to use compliance with a CGMP requirement as justification for whether or not a hazard would require a preventive control. If so, the facility would need to keep records in order to provide the justification to support the hazard analysis determination in the food safety plan.

Slide 43

In summary, the CGMP requirements provide the foundation necessary for the production of safe animal food. While CGMP requirements must be implemented in accordance with the *Preventive Control for Animal Food* rule, they are managed outside of the food safety plan and do not require documentation. However, because the CGMP covers all areas of animal food manufacturing, including personnel, facilities, and operations, it is vitally important that the specifics are understood, and that all individuals involved in the manufacturing, processing, packing, and holding of animal food are trained as necessary in order to effectively carry out their assigned duties in a manner that satisfies the requirements.