



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Preventive Controls for Animal Food

Version 1.1 – 2017



Participant Manual

PUBLIC VERSION

FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD *TRAINING CURRICULUM*

Version 1.1 – 2017

Disclaimer

The information provided by the Food Safety Preventive Controls Alliance (FSPCA) is for training purposes only. The FSPCA is not your attorney and cannot provide you with legal advice. The FSPCA curriculum is intended as a training tool to assist companies in complying with the FDA Food Safety Modernization Act (FSMA) preventive controls regulation; however, following this curriculum does not ensure compliance with the law or FDA's regulations. For advice regarding the legal compliance with FSMA, please consult your legal counsel.

The information provided by the FSPCA will vary in applicability to each food manufacturer. It is not possible for the FSPCA training curriculum to address every situation. Companies should implement the practices and programs that will function best to produce safe foods based on the nature of their individual operations. FSPCA materials do not outline the only approach to developing and implementing a Food Safety Plan. Companies can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by FSPCA does not create binding obligations for the Food and Drug Administration or industry.

FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided in its curriculum and is not responsible for any errors or omissions or for any results obtained from the use of such information. FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use. In no event shall FSPCA be liable for any indirect, special or consequential damages in connection with any use of this training curriculum.

Developed by the



Version 1.1 contains changes to address technical amendments and corrections published by FDA, and editorial corrections identified in version 1.

Contributors: FSPCA Animal Food Sub-Committee

The FSCPA Animal Food Sub-Committee, Animal Food Editorial Committee, and especially the Animal Food Editor Team, made significant contributions of time and expertise in developing the Food Safety Preventive Controls Alliance training curriculum and supporting documents since its inception in 2012. Affiliations while work was in progress are noted.

Animal Food Editorial Sub-Committee **Animal Food Editor Team members denoted with ***

David C. Ailor, National Oilseed Processors Association (NOPA), Executive Vice President, Regulatory Affairs, Washington, DC

Nick B. Charveron, Archer Daniels Midland Company (ADM), Divisional Quality Control Manager, Decatur, IL

Kelly Davis, Renewable Fuels Association (RFA), Director of Regulatory Affairs, Washington, DC

*Adam Fahrenholz, North Carolina State University (NCSU), Assistant Professor – Feed Milling, Raleigh, NC

*David Fairfield, Chairman, National Grain and Feed Association (NGFA), Senior Vice President of Feed Services, Washington, DC

Matt Frederking, Ralco Nutrition Inc., Vice President, Regulatory Affairs and Quality, Marshall, MN

Charles R. Hurburgh, Jr., Iowa State University (ISU), Food Science and Human Nutrition, Professor of Agricultural and Biosystems Engineering, Ames, IA

Billie Johnson, Simmons Pet Food, Inc., Director of Food Safety, Emporia, KS

*Cassandra Jones, Kansas State University (KSU), Department of Grain Science, Assistant Professor in Feed Technology, Manhattan, KS

Kim Koch, North Dakota State University (NDSU), Animal Science Department, Adjunct Professor and Feed Center Manager, Fargo, ND

*Sonya Lambkin, Project Manager, U.S. Food and Drug Administration (USFDA), Consumer Safety Officer, Rockville, MD

Tim Lyons, Association of American Feed Control Officials (AAFCO), Chair of Education and Training Committee, and Michigan Department of

Agriculture, Feed Safety Specialist, Lansing, MI

David Meeker, National Renderers Association, Inc. (NRA), Senior Vice President of Scientific Services, Alexandria, VA

*Dianne Milazzo, U.S. Food and Drug Administration (USFDA), Consumer Safety Officer, Richmond, VA

*Brandi Miller, Kansas State University (KSU), IGP Institute, Interim Associate Director, Manhattan, KS

*Jenny Murphy, U.S. Food and Drug Administration (USFDA), Consumer Safety Officer, Rockville, MD

Ansen Pond, Darling International, Inc., Product Safety Manager, Irving, TX

*Charles Stark, Kansas State University (KSU), Department of Grain Science, Associate Professor in Feed Technology, Manhattan, KS

*Patrick M. Tovey, Vice-Chairman, Pet Food Institute (PFI), Director, Technology and Regulatory Compliance, Washington, DC

*Henry Turlington, American Feed Industry Association (AFIA), Director of Quality and Manufacturing Regulatory Affairs, Arlington, VA

Amanda Yotty, Kent Nutrition Group Inc., Manager, Regulatory Affairs, Muscatine, IA

Hazard Analysis and Preventive Controls for Animal Food Training

The Food Safety Preventive Controls Alliance developed this training curriculum in Food Safety Preventive Controls compliant with the FDA's *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals* regulations. For the most current course information, please consult: <http://www.iit.edu/ifsh/alliance/>



This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the Food and Drug Administration to the Illinois Institute of Technology's Institute for Food Safety and Health. The views expressed herein do not necessarily reflect the views of these organizations. Direct all inquiries to the FSPCA at fspca@iit.edu

TABLE OF CONTENTS

Preface: Introduction to Course	P-1
Chapter 1: Regulatory Overview and Introduction to the Rule.....	1-1
Chapter 2: Current Good Manufacturing Practice	2-1
Chapter 3: Animal Food Safety Hazards	3-1
Chapter 4: Overview of the Food Safety Plan	4-1
Chapter 5: Hazard Analysis and Preventive Controls Determination	5-1
Chapter 6: Required Preventive Control Management Components	6-1
Chapter 7: Process Preventive Controls	7-1
Chapter 8: Sanitation Preventive Controls.....	8-1
Chapter 9: Supply-Chain-Applied Controls.....	9-1
Chapter 10: Recall Plan	10-1
Appendix 1: Preventive Controls for Animal Food Rule	A1-1
Appendix 2: Acronyms and Abbreviations Reference	A2-1
Appendix 3: Example Food Safety Plan	A3-1

PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

PREFACE. Introduction to Course



Slide 1

The *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals* regulation (hereafter referred to as the *Preventive Controls for Animal Food*, or PCAF rule) can be found in Title 21 of the Code of Federal Regulations (CFR) Part 507 (21 CFR part 507). The *Preventive Controls for Animal Food* rule is intended to ensure safe manufacturing, processing, packing, and holding of animal food products in the United States.

Disclosure

Although I attended the FSPCA Lead Instructor training:

- a) Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
- b) I do not represent, speak for, or act on behalf of the FSPCA;
- c) The FSPCA cannot provide legal advice;
- d) The FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
- e) Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
- f) The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use



Slide 2

It should be noted that the instructor(s) of this course have attended the FSPCA Lead Instructor training, but:

1. Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
2. I do not represent, speak for, or act on behalf of the FSPCA;
3. The FSPCA cannot provide legal advice;
4. The FSPCA does not guarantee the accuracy, adequacy, completeness, or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
5. Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
6. The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use.

Food Safety Preventive Controls Alliance

- The *FSPCA Preventive Controls for Animal Food* course is the “standardized curriculum” recognized by FDA
- Successfully completing this course is one way to meet the requirements for a *Preventive Controls Qualified Individual*.



Slide 3

The PCAF regulation requires that certain activities must be completed by a *Preventive Controls Qualified Individual* who has “successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system.” This is the standardized curriculum recognized by FDA and was designed by regulatory, academic, and industry professionals as part of the Food Safety Preventive Controls Alliance. This course is one way to meet the requirements to be a *Preventive Controls Qualified Individual*.

Course Objectives

Through successful completion of this course, you will:

- Meet training requirements for a *Preventive Controls Qualified Individual* under the *Preventive Controls for Animal Food* rule.
- Distinguish between Current Good Manufacturing Practices (CGMPs), other prerequisite programs, and preventive controls and where they fit into the regulatory framework.
- Understand the hazard analysis process and resources to help conduct an analysis.
- Learn concepts needed to build a Food Safety Plan.



Slide 4

The course will help participants meet the training requirements for a *Preventive Controls Qualified Individual*. Upon successful completion of the course, participants will be able to distinguish between Current Good Manufacturing Practices (CGMPs), other prerequisite programs, and preventive controls and understand how they fit into the regulatory framework so that hazards are adequately controlled. The course will also help participants understand the hazard analysis process and how to use available resources to conduct a thorough analysis. The course's final outcome is to learn concepts needed to build a Food Safety Plan.

What is Not Intended by this Course?

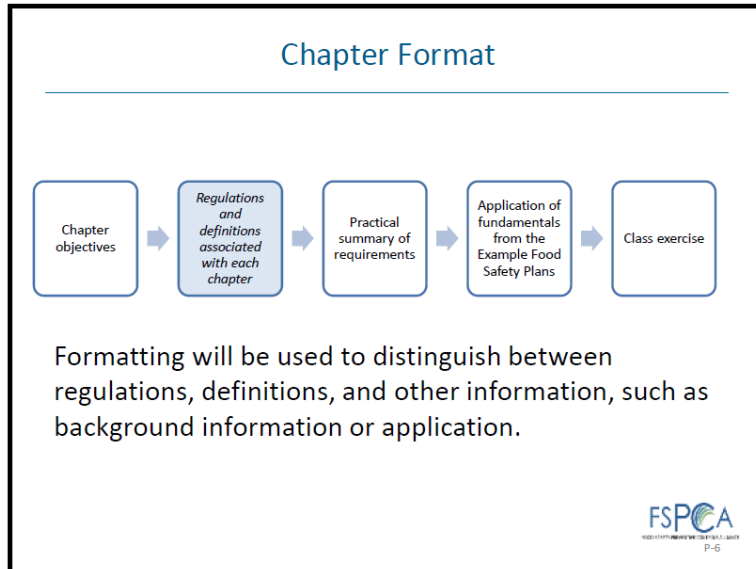
- A complete Food Safety Plan for individual facilities will not be developed during this course.
- Focus should not be on 'how to pass an inspection.'
 - Instead, concentrate on the *concepts* of implementing a food safety plan, which will improve communication of the facility's food safety system to:
 - Suppliers of raw materials or ingredients
 - Customers of finished product
 - Employees
 - Regulatory authorities



Slide 5

While this course will accomplish the objectives laid out in Slide P-4, it is also important for participants to know what is not intended by this course. While the course will teach the concepts of how to develop and implement a Food Safety Plan, participants will not be developing a plan for their own facility in this course. The process of developing a Food Safety Plan typically takes multiples days or weeks, and usually requires input from a number of individuals within the facility and within the business. Instead, this course will help teach the requirements for a Food Safety Plan and will lay out how some of those requirements may be applied through different examples.

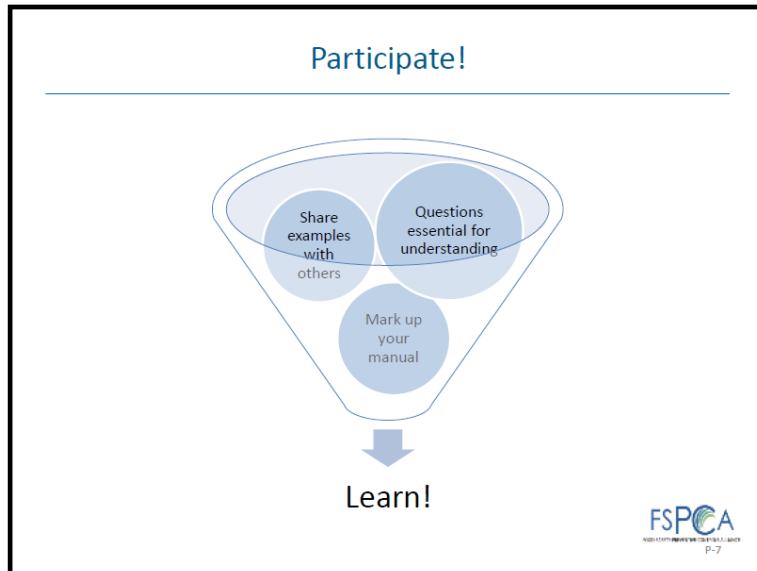
In addition, this course is NOT intended as a path for 'how to pass a FSMA inspection.' Participants should approach the course as a way to learn and implement the concepts of the *Preventive Controls for Animal Food* rule. Fulfilling the requirements outlined in the rule is certainly important to ensuring regulatory compliance, but it also leads to more thorough communication of a facility's food safety system with suppliers of its ingredients or raw materials, consumers purchasing or using its animal food, and new or continuing employees charged with safely manufacturing, processing, packing, or holding its animal food.



Slide 6

In general, the format of the individual chapters in this curriculum are divided into five parts. There are exceptions to this format, but for the most part, chapters are divided into the following five parts:


1. Objectives. These provide direction for the primary concepts participants should take away from each section.
2. Relevant regulations and definitions. A summary of the relevant regulations and definitions is provided at the start of each chapter. Note that the full regulation is provided as Appendix 1. In addition, a summary of relevant acronyms is provided as Appendix 2. Reviewing the regulatory language and definitions relevant to each chapter will help provide context. Whenever regulatory language or definitions from the rule are used in this training, they are designated by slides having a shaded box that will be blue if printed in color and *italicized font*.
3. Practical summary of requirements. These slides will provide examples of approaches that may be used to reach the requirements of the regulation. It is important to note that the industry good practice examples and different approaches provided throughout the course are optional, and do not necessarily represent policy or requirements.
4. Application of fundamentals. Examples from two example Food Safety Plans have been constructed to help illustrate concepts of application. These examples are solely examples that are based on fictional facilities, and are not necessarily applicable to other facilities. However, they are intended to help participants understand the concepts utilized in the curriculum.
5. Follow-up exercise. To help participants understand how the concepts may be applied, these exercises have been designed to apply concepts learned during the lecture. They may be completed in groups or individually. The training exercise workbook is a separate document.



Slide 7

Different individuals have different learning styles. While some may be able to absorb all that is needed by reading the *Preventive Controls for Animal Food* rule or listening as the rule is described, the nuances and requirements are easier for other participants to understand through a dialogue. That means that questions from participants are essential for understanding the course material, and they are encouraged at any time. Participants should share examples they may have had regarding the implementation of similar concepts with others, and take full advantage of the exercises. Finally, they should not be afraid to write in the manual. The manual is for participants to take home after the training, so writing in the margins, highlighting, and making notes as needed is encouraged to remind participants of key components. All these may be useful ways to help learn and apply the concepts when the participants are back at their facilities.

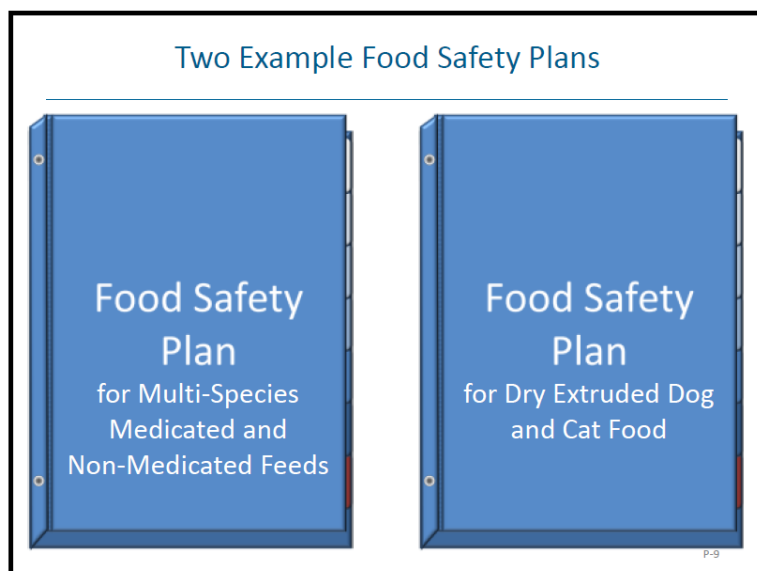
Curriculum Layout	
Number	Title
1	Regulatory Overview and Introduction to the Rule
2	Current Good Manufacturing Practice
3	Animal Food Safety Hazards
4	Overview of the Food Safety Plan
5	Hazard Analysis and Preventive Controls Determination
6	Preventive Control Management Components
7	Process Controls
8	Sanitation Controls
9	Supply-Chain Applied Controls
10	Recall Plan
Appendix 1	Preventive Controls for Animal Food Rule
Appendix 2	Acronyms and Abbreviations Reference
Appendix 3	Example Food Safety Plan



P-8

Slide 8

Chapters 1 through 10 will be presented as lectures in this training, and Appendices 1 through 3 have been provided so participants can refer to the detailed information during this course. The chapters will cover all the necessary components that one must understand to successfully write and implement a Food Safety Plan. In addition to the appendices already described, Appendix 3 contains an abridged example animal Food Safety Plan that is discussed throughout the training. The Food Safety Plans are described in more detail on the next slide. However, it is important to note that these are abridged plans and not representative of all components or required length.

**Slide 9**

As stated, this curriculum has examples from two different Food Safety Plans: 1) one from a commercial feed mill that manufactures animal food for dairy, beef, sheep, swine, poultry, and equine species, and 2) one from a facility that manufactures dry extruded dog and cat food. The two Food Safety Plans shown throughout the curriculum are incomplete plans because the goal is to demonstrate key concepts, not to provide completed plans. The example plan for dry extruded dog and cat food is included as Appendix 3 so participants can see the potential layout of a Food Safety Plan.

Note – These are Just Examples

- Each facility has different considerations.
 - Examples used throughout this curriculum are just that – examples.
 - Some facilities may have hazard analyses, hazard control strategies, and Food Safety Plans similar to those shown within this curriculum.
 - Other facilities may have hazard analyses and controls with different outcomes or Food Safety Plans with different formats.
 - As long as all required components are present and applied appropriately, the format and specific content of Food Safety Plans may vary widely.



Slide 10

As previously mentioned, the example Food Safety Plans used throughout this curriculum are just examples. Each facility has different considerations. Some facilities may have hazard analyses, hazard control strategies, and Food Safety Plans similar to those shown within the curriculum. Other facilities may have different outcomes following their hazard analysis and selection of hazard control strategies, or their Food Safety Plans may have different formats than those shown in this curriculum. As long as all the required components of the *Preventive Controls for Animal Food* rule are present and applied appropriately, the format and the specific content of the Food Safety Plans may vary widely.

FSPCA Contact Information

If you have any questions,
please contact the FSPCA at
fspca@iit.edu
or or visit the FSPCA website at
<http://www.iit.edu/ifsh/alliance>
for resources on preventive controls and information on
FSPCA activities.



Slide 11

If participants have questions, they can contact the Food Safety Preventive Controls Alliance at FSPCA@iit.edu or visit the website at the address listed on the slide. This website has a number of resources on preventive controls and information on FSPCA activities.

NOTES

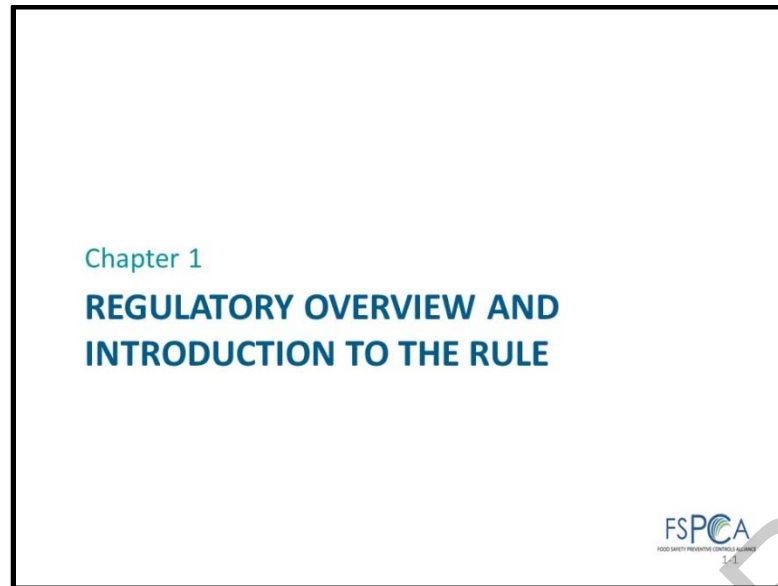
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

CHAPTER 1. Regulatory Overview



Slide 1

As a reminder, this course is one way to meet the requirements to be a *Preventive Controls Qualified Individual*. The course will help participants distinguish between Current Good Manufacturing Practices (CGMPs), other prerequisite programs, and preventive controls and understand how they fit into the regulatory framework so that hazards are adequately controlled. The course will also help participants understand the hazard analysis process and how to use available resources to conduct a thorough analysis. The course's final outcome is to learn concepts needed to build a Food Safety Plan.

Participants will not walk away from this course with a completed Food Safety Plan for a specific facility. The course will discuss different examples as a way to help participants understand core concepts. This course is to help participants understand how to write and implement the required components of a Food Safety Plan as a part of a larger food safety system, not to write a specific plan. Development of the Food Safety Plan for a specific facility likely needs to be done with consultation of the facility's food safety team and may take weeks to complete.

Objectives for Regulatory Overview and Introduction to the Rule

In this chapter, you will develop an awareness of:

- The requirements of 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- Learn the requirements of the following subparts:
 - Subpart A – General Provisions
 - Subpart D – Withdrawal of a Qualified Facility Exemption
 - Subpart F – Requirements Applying to Records That Must be Established and Maintained
- Note that subparts B, C, E will be covered more in depth in other chapters.



Slide 2

In this chapter, participants will develop an awareness of the requirements of the *Preventive Controls for Animal Food* rule, learn some background information on the Food Safety Modernization Act (FSMA) and the *Preventive Controls for Animal Food* rule, and learn some of the specific requirements of subparts A, D, and F. Note that subparts B, C, and E will be summarized in this chapter, but are covered in more depth in later chapters.

Significant Animal Food Laws and Regulations

- 1906 Pure Food & Drug Act
- 1938 Federal Food, Drug & Cosmetic Act
- 1958 Food Additives Amendment
- 1976 Medicated Feed CGMPs
- 1996 Animal Drug Availability Act (VFDs)
- 1997 BSE/Ruminant Feed Regulations
- 2002 Bioterrorism Preparedness and Response Act
- 2007 Food and Drug Administration Amendments Act
- 2011 Food Safety Modernization Act (FSMA)
- 2014 Veterinary Feed Directive Revised Regulations



Slide 3

It is sometimes helpful to reflect on other significant laws and regulations enacted that impact animal food safety. Many of these laws and regulations helped form the foundation for animal food safety regulations prior to the *Preventive Controls for Animal Food* rule, while others are tangential to its objective.

The existing laws and regulations for animal food established a framework for regulation of animal food in the United States. From the definitions established in the Federal Food, Drug, and Cosmetic Act to the concepts of Current Good Manufacturing Practices, compliance inspections, recordkeeping, hazard control, and traceability, all of these previously existing laws and regulations set a foundation for the basis of the *Preventive Controls for Animal Food* rule. The *Preventive Controls for Animal Food* rule was developed as directed by Congress in FSMA. The *Preventive Controls for Animal Food* rule and the existing laws and regulations will work together to ensure the safety of the U.S. animal food supply.

FSMA Snap Shot

Signed into law January 4, 2011

- The current food safety system has opportunity for improvement.
 - 1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011)
- Identified by FDA as the most sweeping reform of food safety laws in more than 70 years.
 - GOAL: Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

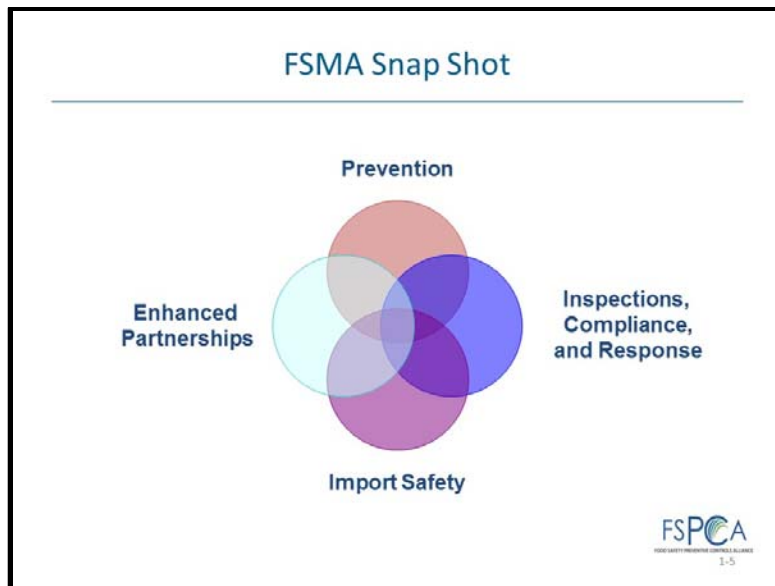


Slide 4

FSMA was signed into law in January 2011. The bill was drafted because Congress felt that current food safety had the opportunity for improvement. At the time the law was passed, data from the Centers for Disease Control and Prevention (CDC) reported that 1 in 6 Americans, which is approximately 48 million people, were sickened, 128,000 hospitalized, and 3,000 died each year from foodborne diseases.

Animal food can cause illness and potentially death in humans who either contact the animal food or who consume the edible products (e.g., meat, milk, and eggs) of animals who eat contaminated food. Animal food can also cause illness or death of animals, which includes both pet animals and food-producing animals. Given the complex nature of the animal food supply and increasing globalization of the animal food supply, animal food was also incorporated into FSMA so that animal food hazards impacting animal and human health were controlled throughout the food supply.

The FDA has described FSMA as the most sweeping reform of our food safety laws in more than 70 years. This is quite the statement considering that several of the laws and regulations described on the previous slide had major impacts on the animal food industry. The goal of FSMA is to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

**Slide 5**

There are four main themes of FSMA: prevention, enhanced partnerships, import safety, and inspections/compliance/response. These themes mandate FDA to:

1. Enhance partnerships between domestic and foreign government agencies, such as through the creation of the domestic integrated food safety system;
2. Help ensure that imported food meets U.S. food safety standards;
3. Conduct food facility inspections at a required frequency and utilize new tools to ensure compliance and respond more quickly when food safety problems are detected; and
4. Create a regulatory system that prevents the occurrence of food safety hazards.

It is Theme 4: Prevention that is the focus of the *Preventive Controls for Animal Food* rule described by this curriculum.

FSMA Snap Shot

This course covers just one of many rules created under the framework of FSMA.

1. Preventive Controls for Animal Food
2. Preventive Controls for Human Food
3. Produce Safety
4. Foreign Supplier Verification Programs (FSVP) for Importers
5. Sanitary Transportation of Human and Animal Food
6. Accredited Third-Party Certification
7. Mitigation Strategies to Protect Food Against Intentional Adulteration



Slide 6

Congress directed FDA to create regulations to fully implement the four themes of FSMA. Because FSMA is so multifaceted, many rules are required for its implementation. The initial rule making has resulted in seven major rules that together form the new foundation for food safety for human and animal food. The seven major final rules were published between September 2015 and May 2016.

Applicability to FSMA Rules to Animal Food

Rules <u>applicable</u> to Animal Food	Rules <u>NOT</u> applicable to Animal Food
Preventive Controls for Animal Food	Preventive Controls for Human Food
Foreign Supplier Verification Program	Produce Safety
Accredited Third-Party Certification	Intentional Adulteration
Sanitary Transportation	



This course only covers Preventive Controls for Animal Food. The FDA website and guidance documents can help provide further information on other rules, as can other training courses developed by the Food Safety Preventive Controls Alliance.

Slide 7

Of the seven major final FSMA rules, only 4 of the 7 have application to the animal food industry. The *Preventive Controls for Animal Food*, *Foreign Supplier Verification Program*, *Accredited Third-Party Certification*, and *Sanitary Transportation of Human and Animal Food* rules all have application for the animal food industry. Of these four rules, the two with the broadest and most immediate implications are the *Preventive Controls for Animal Food* and *Foreign Supplier Verification Program* rules.

The three major FSMA rules that do NOT apply to animal food are the rules for *Preventive Controls for Human Food*, *Produce Safety*, and *Intentional Adulteration*.

There are separate training requirements and standardized curricula for some of the other rules. For example, there are separate FSPCA course for the *Preventive Controls for Human Food* rule and the *Foreign Supplier Verification Program* rule. This curriculum will focus only on the *Preventive Controls for Animal Food* rule.

Preventive Controls for Animal Food Timeline

- January 2011: FSMA signed into law
- October 2013: First version issued (Proposed Rule)
- September 2014: Second version issued (Revised Rule)
- September 2015: Final rule published

Business Size	Subpart B Current Good Manufacturing Practice	Subpart C Hazard Analysis and Risk-Based Preventive Controls
All Others	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 18, 2017	Sept. 17, 2018
Very Small Businesses (< \$2.5 million/year)	Sept. 17, 2018	Sept. 17, 2019

1-8

Compliance dates for Subpart E (Supply-Chain Program) vary based on several factors. See Table 33 in the preamble to the Final Rule (page 56329) at:
<https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf>

Slide 8

January 2011 saw the signing of FSMA by President Obama. The first version of the *Preventive Controls for Animal Food* rule was published as a proposed rule in October 2013. A supplemental proposal that provided revisions to the proposed rule was issued in September 2014, and the final rule was published on September 17, 2015.

There are two major subparts to the rule – the Current Good Manufacturing Practice (CGMP) requirements found in 21 CFR part 507, subpart B and the Hazard Analysis and Risk-Based Preventive Controls requirements found in 21 CFR 507, subpart C. Because the animal food industry will be implementing both CGMPs and preventive controls for the first time, the compliance dates were staggered for the implementation of these subparts based on business size:

- Businesses with more than 500 employees must comply with the Current Good Manufacturing Practice requirements by September 19, 2016 and the Hazard Analysis and Risk-Based Preventive Controls by September 18, 2017.
- Small businesses must comply with CGMP requirements by September 18, 2017 and the Hazard Analysis and Risk-Based Preventive Controls by September 17, 2018.
- Those that meet the definition of a *Very Small Business*, which is a type of *Qualified Facility*, will have to comply with CGMP requirements by September 17, 2018 and with Hazard Analysis and Risk-Based Preventive Controls by September 17, 2019.

21 CFR Part 507 – Preventive Controls for Animal Food

- *Subpart A – General Provisions*
- *Subpart B – Current Good Manufacturing Practice*
- *Subpart C – Hazard Analysis and Risk-Based Preventive Controls*
- *Subpart D – Withdrawal of a Qualified Facility Exemption*
- *Subpart E – Supply-Chain Program*
- *Subpart F – Requirements Applying to Records That Must Be Established and Maintained*



Slide 9

Here is the first slide with a blue outlined box and italics. That is a cue that the slide is referencing the regulation, not just examples or recommendations for its application. Note that this chapter has a lot of blue boxes as there will be a lot of regulatory concepts reviewed here. Other chapters tend to have less focus on the regulation as they are more focused in scope.

The *Preventive Controls for Animal Food* rule has 6 subparts (see Appendix 1 for a copy of the regulation in its entirety and Appendix 2 for a technical amendment to the rule). The subparts include:

- Subpart A: General Provisions, including training requirements and applicability
- Subpart B: Current Good Manufacturing Practice requirements
- Subpart C: Hazard Analysis and Risk-Based Preventive Controls
- Subpart D: Requirements for withdrawal of a *Qualified Facility's* exemption status by FDA
- Subpart E: Supply-Chain Program requirements
- Subpart F: Requirements applying to records that must be established and maintained

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart A – General Provisions

- 507.1 *Applicability and status.*
- 507.3 *Definitions.*
- 507.4 *Qualifications of individuals who manufacture, process, pack, or hold animal food.*
- 507.5 *Exemptions.*
- 507.7 *Requirements that apply to a qualified facility.*
- 507.10 *Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.*
- 507.12 *Applicability of this part to the holding and distribution of human food by-products for use as animal food.*



The Preamble is where the FDA has provided additional context and answered the public comments to the *Preventive Controls for Animal Food* rule. If there are additional questions about a section of the regulations, it is often helpful to read the corresponding section of the Preamble. The Preamble reflects the FDA's current thinking of the time of rule writing.

Because the rule with the Preamble is 188 pages, only the 20 pages of codified language is included in this training material. The full Federal Register notice with Preamble can be found at <https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf>.

Slide 10

The General Provisions in subpart A are broken into sections that describe the rule's applicability and status, definitions, qualifications of individuals who manufacture, process, pack, or hold animal food, exemptions, requirements that apply to a *Qualified Facility*, applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food, and applicability of this part to the holding and distribution of human food by-products for use as animal food. Each of these sections will be described next.

It is suggested that participants follow along with the regulatory text in Appendix 1. The content of Appendix 1 is the final rule printed from the Federal Register. The whole rule in this format, including the Preamble, is 188 pages long according to the Federal Register. The last 20 pages are provided, which is the codified portion of the rule. The first section is Section 507.1, the Applicability and Status of the rule. That section begins on the first page of Appendix I, which is page number 56337 of volume 80 of the Federal Register.

21 CFR 507.1 Applicability and status

- (a) *The criteria and definitions in this part apply in determining whether an animal food is:*
 - (1) *Adulterated within the meaning of:*
 - (i) *Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or*
 - (ii) *Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and*
 - (2) *In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).*



The determination if specific facilities meet the applicability or exemptions described by the *Preventive Controls for Animal Food* rule is outside the scope of this course. Questions regarding applicability may be directed to the FDA via the online Technical Assistance Network portal available through: www.fda.gov/fsma.

Slide 11

An animal food does not need to contain a harmful substance to be adulterated. The Federal Food, Drug, and Cosmetic Act (Sections 301(a) and (k)) prohibits introducing or delivering for introduction into interstate commerce adulterated animal food, and doing an act (e.g., violating CGMPs or preventive controls) that causes animal food to become adulterated after receipt of that food or its components in interstate commerce while the food is held by a facility for sale.

Among other remedies, the government has authority to file actions in court to remove adulterated animal food from the marketplace (seizure) and/or to prevent a firm from continuing to manufacture and distribute adulterated food (injunction; Sections 304 and 302). Following the CGMP and preventive controls requirements for animal food is important because it may help prevent an animal food facility from producing and distributing adulterated animal food.

Ultimately, the failure to comply with the *Preventive Controls for Animal Food* rule may result in FDA determining an animal food is adulterated because it was manufactured under conditions unfit for food, or it was prepared, packed, or held under insanitary conditions where it may have been contaminated.

21 CFR 507.1 Applicability and status

- *(b) The operation of the facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 415 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and §507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.*
- *(c) Animal food covered by specific current good manufacturing practice regulations is also subject to the requirements of those regulations.*



Slide 12

The *Preventive Controls for Animal Food* rule applies to all facilities that are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act because they manufacture, process, pack, or hold animal food for consumption in the United States. There are some exemptions and modified requirements for certain registered facilities, which are discussed later. Establishments, such as farms, are exempt from registration and are therefore not subject to the requirements of 21 CFR part 507. Both domestic animal food manufacturing facilities and foreign facilities importing food into the U.S. must comply with the rule.

In addition to regulations outlined in this rule, facilities must still comply with other regulations that apply to the type of animal food they are manufacturing, such as regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR 113) and Current Good Manufacturing Practice for Medicated Feeds (21 CFR 225).

Who Must Comply?

- Facilities that manufacture, process, pack, or hold animal food for consumption in the United States
 - In general, those that register under Section 415 of the Federal Food, Drug, and Cosmetic Act (Bioterrorism Act).
 - Not complying is considered a prohibited act.
- Animal food covered by specific CGMP regulations must still comply with those regulations
 - Low-acid canned food
 - Medicated feed



Slide 13

To summarize, the rule is applicable to facilities that register as an animal food facility under Section 415 of the Federal Food, Drug, and Cosmetic Act. If facilities do not comply, it is a prohibited act. Facilities that are already subject to other animal food safety regulations, such as medicated feed CGMPs, must continue to abide by those regulations in addition to the requirements found in the *Preventive Controls for Animal Food* rule.

21 CFR 507.3 Definitions

- *The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.*
- Discussed throughout individual chapters



Slide 14

The definitions found in 21 CFR 507.3 include definitions found in section 201 of the Federal Food, Drug, and Cosmetic Act and the specific definitions that are also listed in 21 CFR 507.3. This curriculum will not walk through each definition in 21 CFR part 507. Instead, it will cover them as the need arises throughout the training. The official definitions begin on page 2 of Appendix 1, which is page 56338 of the Federal Register.

21 CFR 507.4 Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- *(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and*
- *(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.*



Slide 15

The next section describes the required qualifications of an individual who is directly involved in manufacturing, processing, packing, or holding animal food. For establishments subject to CGMP and recordkeeping requirements (21 CFR part 507, subparts B and F), the management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties. For facilities subject to hazard-analysis and risk based preventive control, supply-chain program, and recordkeeping requirements (21 CFR part 507, subparts C, D, E, and F), the owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties.

21 CFR 507.4 Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- (b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:
 - (1) Be a qualified individual as that term is defined by §507.3 i.e. have 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; and
 - (2) 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.



Slide 16

Any individual, including temporary and seasonal personnel, engaged in manufacturing, processing, packing, or holding of animal food or the supervision of those activities must be a *Qualified Individual* as defined in section 507.3. He or she must have 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.

In addition, the individual must 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. Records of training in the principles of animal food hygiene and animal food safety must be documented.

21 CFR 507.4 Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- *(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.*
- *(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.*



Slide 17

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. Those records are subject to the requirements outlined in 21 CFR part 507, subpart F, which will be described at the end of this chapter.

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.



Slide 18

Qualified Individual is a defined term in the definitions section of the rule. The requirements for training, established in subpart A, apply to individuals engaged in manufacturing, processing, packing, or holding food regardless of whether the individuals conduct these activities under the framework of the CGMPs established in subpart B and F or the framework for hazard analysis and risk-based preventive controls established in subparts C, D, E, and F.

Note that a *qualified individual* may or may not be an employee of an establishment. Individuals, even if he or she is a temporary or seasonal worker, must be qualified to perform their assigned duties.

What are the Qualifications of Individuals?

- All individuals who manufacture/process/pack/hold animal food must be qualified to perform their assigned duties:
 - Includes temporary and seasonal workers
 - Must be a *Qualified Individual* as defined by § 507.3
 - Have education, training, experience, or a combination thereof, to complete duties in a way that results in safe food.
 - Receive training on animal food hygiene and safety, including importance of employee health and personnel hygiene as appropriate.
- The responsibility for this assurance changes:
 - Subpart B: Management of an establishment
 - Subpart C: Owner, operator, or agent in charge of the facility



The 'education or training' referred to in this section means training by any reasonable means. 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. Individuals currently involved with manufacturing, processing, packing, or holding animal food at the facility are to be trained by the first compliance date for the *Preventive Controls for Animal Food* rule that applies to the facility.

Slide 19

To summarize, all individuals associated with the specified tasks for animal food, even if they are temporary or seasonal workers, are required to be qualified in order to perform their assigned duties. The language that states "as appropriate to the animal food, the facility, and the individual's assigned duties" demonstrates that there is flexibility in the application of the requirement for training in the principles of animal food hygiene and animal food safety.

There may not be a need for all personnel to have the same level of training in the principles of animal food hygiene and animal food safety. For example, a forklift driver may not be required to undergo as intensive of a training course as an ingredient receiving operator. The forklift driver may rarely come in contact with unpackaged animal food, so his or her training may be geared towards what precautions to take when operating the forklift so that the animal food is not contaminated when it is being moved by the forklift. However, those individuals must have the education, training, experience, or a combination thereof, to complete their duties in a way that results in safe animal food, and they must receive training on animal food hygiene and safety, including the importance of employee health and personnel hygiene, as appropriate. Records to support that training in animal food hygiene and safety are necessary for a facility to maintain.

Finally, the responsibility for the assurance that individuals are qualified changes depending upon the subpart. Management is responsible for assuring that individuals are qualified to perform their assigned duties when the plant is subject to the CGMP requirements in subpart B and F. Meanwhile, the owner, operator, or agent in charge of the facility is responsible for this assurance when the facility is subject to the requirements in subpart C, D, E, and F.

21 CFR 507.3 – Definitions:

“Preventive Controls Qualified Individual”

- A *Qualified Individual* who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.



Slide 20

Another term that is similar to that of a *Qualified Individual* is a *Preventive Controls Qualified Individual*. This *Preventive Controls Qualified Individual* term is defined in 21 CFR 507.3 as a *Qualified Individual* who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that recognized under a standard curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Preventive Controls Qualified Individual(s)

Must oversee:

1. Preparation of the Food Safety Plan
2. Validation of the preventive controls
3. Determination that validation is not required
4. Review of records
5. Reanalysis of the Food Safety Plan
6. Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production
7. Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days
8. Determination that reanalysis can be completed and additional preventive controls validated as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production



Slide 21

Under the regulation (21 CFR 507.53), the *Preventive Controls Qualified Individual* has a lot of responsibility as certain tasks must be performed by someone with those qualifications. This course developed by FSPCA is the “standardized curriculum” recognized by FDA. Successfully completing this course is one way to meet the requirements for a *Preventive Controls Qualified Individual*. Under the *Preventive Controls for Animal Food* rule, some of the responsibilities of a *Preventive Controls Qualified Individual* include to perform or oversee 1) preparation of the Food Safety Plan, 2) validation of the preventive controls, 3) records review and 4) reanalysis of the Food Safety Plan.

The *Preventive Controls Qualified Individual* may be an employee of the facility but the facility can also use outside assistance in developing the Food Safety Plan. In some situations, more than one *Preventive Controls Qualified Individual* may be needed to effectively develop and implement a Food Safety Plan.

21 CFR 507.5 Exemptions

- Establishments, including farms, that are not required to register under § 415 of the Food, Drug, & Cosmetic Act
- Subpart B (CGMP) does not apply to establishments solely engaged in:
 - The holding and/or transportation of raw agricultural commodities.
 - Hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts).
 - Ginning of cotton (without manufacturing /processing, such as extracting oil from cottonseed).



Slide 23

The next section of this chapter is key to understanding who is subject to the *Preventive Controls for Animal Food* rule. Exemptions to the rule or to specific subparts of the rule are found in 21 CFR 507.5. Establishments, such as farms, that are not required to register under section 415 of the Federal Food, Drug, & Cosmetic Act do not need to comply with any part of this rule. The definition of a farm is discussed in more detail later in this chapter. Other establishments that are not required to register include facilities such as retail food establishments, restaurants, pet shelters, and veterinary facilities that provide food to animals.

Subpart B, or the Current Good Manufacturing Practices, are not required for facilities that are (1) solely engaged in the holding and/or transportation of raw agricultural commodities, (2) the hulling, shelling, drying, packing, and/or holding of nuts and hulls (without manufacturing/processing), or (3) the ginning of cotton (without manufacturing/processing).

As with the applicability section, the determination of whether specific facilities meet the exemptions described by the *Preventive Controls for Animal Food* rule is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum. Additional information is available in the rule.

Common questions and their answers were published in December 2016 by FDA in the **Draft Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition) — Revised**. There is also a **Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities** that can help facilities determine if their activities would result in them being classified as a “farm” or a “facility”.

Additional questions regarding rule applicability may be directed to the FDA via the online Technical Assistance Network portal available through: www.fda.gov/fsma.

21 CFR 507.5 Exemptions

- Subparts C and E do not apply to:
 - Activities subject to regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (just those activities, not the whole facility)
 - Activities that are subject to Standards for Produce Safety Rule
 - Qualified Facilities (must follow modified requirements)
 - Small or very small businesses (Qualified Facilities) that are farm mixed-type facilities if the only packing or holding activities are specified low-risk packing or holding activity/animal food combinations, even if activities are for distribution into commerce
 - Facilities solely engaged in storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing



Slide 24

Finally, the hazard analysis and risk-based preventive controls and supply-chain program, which are subparts C and E, do not apply to:

- 1) Activities subject to regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers for the control of microbiological hazards
- 2) Activities that are subject to the produce safety rule.
- 3) A *Qualified Facility*. This definition will be discussed in subsequent slides. While qualified facilities are not subject to 21 CFR part 507, subparts C and E, there are modified requirements applicable to qualified facilities in 21 CFR 507.7.
- 4) A *Small Business* or *Very Small Business* that is a farm mixed-type facility if the only packing or holding activities are specified low-risk packing or holding activity/animal food combinations or low-risk manufacturing/processing activity/animal food combinations, even if the activities are intended to distribute animal food into commerce (for a list of activities, refer to 21 CFR 507.5(e) and (f) respectively).
- 5) Facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

21 CFR 1.227 – Definitions: “Primary Production Farm”

- An operation under one management in one general but not necessarily contiguous physical location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
- May conduct certain manufacturing, processing, packing, or holding activities of animal food as specified.



Note these definitions come from the *Preventive Controls for Human Food (PCHF)* rule, as seen by the different CFR reference. The exact definitions can be found in the PCHF rule, and additional explanation of their applicability can be found in the Preamble of that rule.

The clause that requires “all processed food to be consumed on the farm or another farm under the same management” is key to understanding applicability of the *Preventive Controls for Animal Food* rule to feed mills that may be managed by a farm. The FDA does not consider animals fed at a farm of a contract grower to be under the same management as the feed mill.

Slide 25

To be subject to the requirements of the *Preventive Controls for Animal Food* rule, a facility has to be required to register under section 415 of the Food, Drug, and Cosmetic Act. Farms are one type of establishment that are not subject to registration and are therefore exempt from the requirements of this rule. Farms are defined in 21 CFR 1.227. The definition of a farm is broken into two parts, a *Primary Production Farm*, and a *Secondary Activities Farm*. The *Primary Production Farm* is an operation under one management in one general, but not necessarily contiguous, location that is devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities.

If an operation grows crops, harvest crops, or raises animals, the operation can do additional activities as part of its farming operation, such as:

1. Pack or hold raw agricultural commodities;
2. Pack or hold processed foods, provided that all processed food is consumed on the farm or another farm under the same management; or
3. Manufacture/process food, provided that:
 - a. All food that the farm manufactures/processes is consumed on that farm or another farm under the same management; OR
 - b. Any food not consumed on that farm consists only of manufacturing/processing in the following limited categories
 - Drying/dehydrating raw agricultural commodities to create a distinct commodity;
 - Treatment to manipulate ripening of a raw agricultural commodity; or
 - Packaging and labeling without additional manufacturing/processing.

The raising of animals is outside of the scope of the *Preventive Controls for Animal Food* rule – that is clearly a farming activity. The rule is specific to the manufacturing, processing, packing, or holding of animal food – so the feed mill located on the farm is the part of a farm that is potentially subject to the rule.

21 CFR 1.227 – Definitions:
“*Secondary Activities Farm*”

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those raw agricultural commodities must own or jointly own a majority interest in the secondary activities farm.
- May also pack or hold raw agricultural commodities, or manufacture/process, pack, or hold processed foods so long as all such food is consumed on that farm or another farm under the same management or the manufacturing/processing falls into limited categories.



Slide 26

The *Secondary Activities Farm* was created to address off-farm operations, such as packinghouses owned by farmers. A *Secondary Activities Farm* is an operation not located on a *Primary Production Farm*, but is dedicated to the harvesting, packing, and/or holding of raw agricultural commodities. The *Secondary Activities Farm* must be majority owned by the *Primary Production Farm(s)* that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, or held by the *Secondary Activities Farm*. A *Secondary Activities Farm* may also conduct the additional activities that are allowed on a *Primary Production Farm*.

Impact of Farm Definition on Feed Mills

- Feed mills that are part of a farm are exempt from registering as a food facility and are not subject to rule
- For the feed mill to be part of the farm:
 - Raising animals and feed mill are under same management in one general location, AND
 - Animal food made at the mill is only fed to animals under the farm's management



For a full discussion of changes to the farm definition, refer to the Preamble to the *Preventive Controls for Human Food* rule (pages 55925 to 55932 of vol. 80 of the Federal Register).

For a full discussion of 'fully vertically integrated farming operations' refer to the Preamble to the *Preventive Controls for Animal Food* rule (pages 56184-56185 of vol. 80 of the Federal Register).

Slide 27

Feed mills associated with farming operations have the potential to be subject to the requirements of this final rule. If a feed mill is part of the farm – meaning the feed mill and raising the animals are under the same management, in one general location, and the animal food made at the feed mill is only fed to animals under the farm's management - that feed mill is exempt from registering as a food facility as it falls under the definition of a farm. In the preamble to the final rule, FDA describes this type of farming operation as a “fully vertically integrated farming operation.” Because these types of feed mills are not subject to registration, these feed mills are NOT subject to any part of the rule (CMGPs or preventive controls).

On the opposite side, there are feed mills that are required to register as a food facility under section 415 of the Federal Food, Drug, & Cosmetic Act and are subject to the *Preventive Controls for Animal Food* rule. There are several examples of feed mills required to register, but three key examples include:

1. Commercial or toll mills: The mill produces animal food for sale and is not associated with a farm. The feed mill must register as a food facility and is subject to the rule.
2. Feed mill located off-farm that makes animal food for contract farms – These feed mills are not under the same management as the farms that are responsible for the raising of animals. The feed mill must register as a food facility and is subject to the rule.
3. Farm feed mill with outside customers: The feed mill manufactures food for animals on the farm and under the same management, but also manufactures, processes, packs, or holds food for animals on farms under a different management. The mill must register as a food facility and is subject to the rule.

These are examples of feed mills that are not considered part of farm and are required to register as a food facility. Therefore, these feed mills are subject to the rule.

21 CFR 507.3 – Definitions: “Very Small Business”

- A business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g. held for fee or supplied to a farm without sale).



As with the exemption section, an in-depth discussion of business sizes is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum.

In 2016, FDA released **Guidance for Industry #241: Small Entity Compliance Guide – What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507)**.

Additional information is available in the rule or the FDA Guidance for Industry regarding Qualified Facilities. Additional questions regarding rule applicability may be directed to the FDA Technical Assistance Network.

Slide 28

If a facility does not meet the exemptions described by the farm definitions and registers as a food establishment, it must comply with the *Preventive Controls for Animal Food* rule.

However, there are some additional exemptions and delayed compliance dates for *Qualified Facilities*. A *Very Small Businesses* is one type of *Qualified Facility*.

A *Very Small Business* is a business (including any subsidiaries and affiliates) averaging less than \$2,500,000 adjusted for inflation, per year, during the 3-year-period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale, such as that held for a fee or supplied to a farm without sale.

21 CFR 507.3 – Definitions:
“Qualified Facility”

- (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:
 - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
 - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.



A guidance document for *Qualified Facilities* has been developed by FDA. The guidance document provides information to assist facilities with determining whether they are a *Very Small Business*, including how to calculate the inflation adjusted average and market value. The guidance can be found at:
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>.

A discussion of how to value animal food without sale can be found in the Preamble of the *Preventive Controls for Animal Food* rule.

To fully understand the requirements of Option 2 of the qualified facility definition, you should review the definition for the *Qualified End-User* in 21 CFR 507.3.

Slide 29

A *Qualified Facility* is a facility that is a

- Option 1: *Very Small Business*; **OR**
- Option 2: A facility to which both of the following apply:
 1. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to *Qualified End Users* during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
 2. The average annual monetary value of all food sold during the 3-year prior preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

The majority of animal food facilities that meet the definition of a *Qualified Facility* are expected to be a *Very Small Business* (Option 1), and not many animal food facilities are expected to meet Option 2 of the *Qualified Facility* definition.

21 CFR 507.7 Requirements that Apply to a Qualified Facility

- Qualified facilities must submit attestations to the FDA that the facility:
 - Meets the “qualified facility” definition
 - Must determine status by July 31 of each calendar year.
 - Records to support status must be retained beginning January 1, 2017, but do not need to be part of the attestation.
 - Meets one of the following:
 - Option 1: Has identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure such controls are effective
 - Option 2: Is in compliance with state, local, county, tribal, or other applicable non-federal food safety laws.
- Initial attestations must be submitted by December 2019, and resubmitted every two years beginning in 2020.



Slide 30

A *Qualified Facility* must comply with the Current Good Manufacturing Practices in subpart B and the qualified individual training requirements in 21 CFR 507.4, but is exempt from hazard analysis and risk-based preventive controls (21 CFR part 507, subpart C) and requirements for a supply-chain program (21 CFR part 507, subpart E). Therefore, a *Qualified Facility* is not required to utilize a PCQI within their food safety system, since a PCQI is required to oversee specified requirements established in subpart C. However, the facility is subject to other specific requirements that are found in 21 CFR 507.7. Some may refer to these requirements as “modified requirements.”

A *Qualified Facility* must submit required attestations to the FDA. The first attestation that the facility must submit is that it meets the definition of a *Qualified Facility*. Each qualified facility must determine its own status by July 31 of each calendar year, and the records to support this status must be retained beginning January 1, 2017. The facility must maintain the records (such as financial documents) to support that status. These records may include the three-year average of sales that qualify them as a *Very Small Business* or *Qualified Facility* status. These records do not have to be sent to FDA as part of the attestation.

The facility has a choice between two options for its second attestation. Option 1 is an attestation that the facility has identified potential hazards in its animal food and is implementing, and subsequently monitoring preventive controls. Option 2 is an attestation that the facility is in compliance with state, local, county, tribal, or other applicable non-Federal food safety law.

The first time a *Qualified Facility* must submit its initial attestation is by December 16, 2019. After the initial attestation, attestation must be submitted every 2 years (to coincide with the biennial registration renewal) beginning in 2020.

21 CFR 507.10 Applicability of subparts C and E of this Part to a Facility
Solely Engaged in the Storage of Unexposed Packaged Animal Food.

- (a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.
- (b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.



Slide 31

Section 507.10 of the regulation discusses the applicability of the requirements for hazard analysis and risk-based preventive controls (subpart C) and the supply-chain program requirements (subpart E) to facilities that are “solely engaged in the storage of unexposed packaged animal foods,” such as warehouses.

If a warehouse’s only function is to store unexposed packaged animal food that does not require time/temperature control to control pathogens – the warehouse is exempt from the requirements for subparts C and E.

If a warehouse’s only function is to store unexposed packaged animal food that does require time/temperature control to control pathogens – the warehouse is exempt from the full requirements of subparts C and E, but the warehouse would be subject to the modified requirements for this type of facility as specified in 21 CFR 507.51 as outlined next.

507.51 Modified Requirements that Apply to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food

- If animal food requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, the facility storing the animal food must:
 - Establish and implement temperature controls
 - Monitor temperature controls
 - Take corrective actions if there is a loss of temperature
 - Verify that temperature controls are consistently implemented
 - Establish and maintain records of monitoring, corrective action, and verification



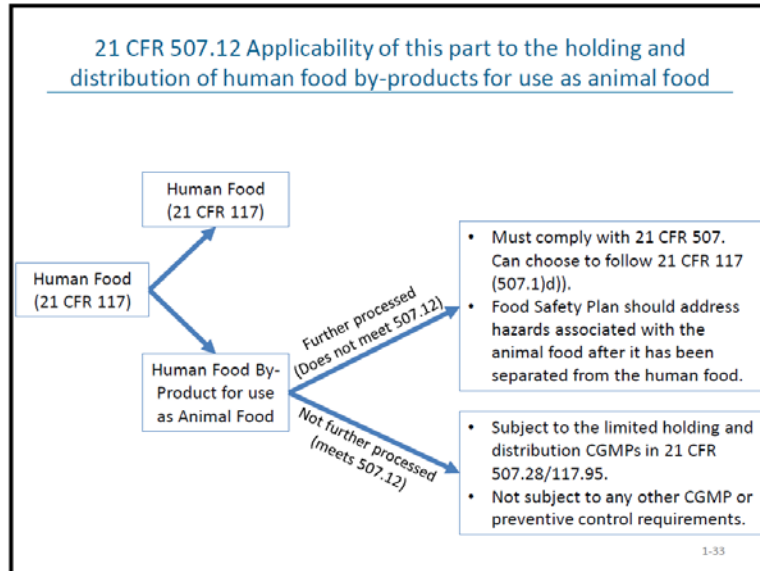
As with the exemption section, an in-depth discussion of these modified requirements is outside the scope of this course. For this reason, the full context of this section is not reviewed in the curriculum. Additional information is available in the rule. Questions regarding rule applicability may be directed to the FDA via the online portal available through: www.fda.gov.

Slide 32

Animal food facilities, such as a warehouse, that are solely engaged in storage of unexposed packaged animal food that requires time/temperature controls to control a pathogen are not subject to the full requirements of subpart C and E. Instead they are subject to modified requirements in 21 CFR 507.51.

If animal food requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, the facility storing the animal food must:

- Establish and implement temperature controls that can control the growth (or toxin formation) of a pathogen.
- Monitor the implemented controls at a frequency determined to be adequate by the facility.
- Take corrective actions if there is a loss of temperature.
- Verify that temperature controls are consistently implemented.
- Establish and maintain records of monitoring, corrective action, and verification.



For additional information on human food by-products for use as animal food, please refer to
**Draft Guidance for Industry # 239:
 Human Food By-Products for Use as
 Animal Food.**

Slide 33

The next section clarifies the applicability of subparts B, C, and E to the holding and distribution of human food by-products for use as animal food.

If a human food facility is producing a human food by-product for distribution as animal food, and:

- 1) the animal food is subject to and in compliance with the human food CGMP regulations (21 CFR part 117), and
- 2) The facility does not further manufacture or process the by-products intended for use as animal food,

Then the facility must follow limited holding and distribution CGMP requirements from 21 CFR 507.28 after the animal food has been separated from the human food. The facility would not need to follow the rest of the requirements in subpart B, C, or E for part 507.

The holding and distribution of human food by-product for use as animal food requirements are located in both the human food requirements (21 CFR 117.95) and the animal food requirements (21 CFR 507.28). There is a similar provision regarding by-products from facilities that are subject to and in compliance with the requirements for off-farm packing and holding of human food produce that are distributed for use as animal food.

For facilities that do not meet the conditions described in 507.12 and are producing human and animal food at their facility, they have the option of following the human food CGMPs and preventive controls requirements in 21 CFR part 117 or the animal food requirements in part 507 for the production of their animal food. Depending on its operations, a facility may feel it is more appropriate to follow one set of regulations instead of two.

For example, if a facility has separate employees, production lines, and holding areas for its human food and animal food, it might prefer to follow part 117 for the human food and part 507 for the animal food. However, if a facility is using common employees, production lines, or holding areas for the human and animal food, it might prefer to follow part 117 for both the human and animal food.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart B – Current Good Manufacturing Practice

- 507.14 Personnel
- 507.17 Plant and grounds
- 507.19 Sanitation
- 507.20 Water supply and plumbing
- 507.22 Equipment and utensils
- 507.25 Plant operations
- 507.27 Holding and distribution
- 507.28 Holding and distribution of human food by-products for use as animal food




Slide 34

That concludes subpart A, but there are six subparts total. Subpart B will have its own chapter and it will be discussed in Chapter 2. Chapter 2 describes the Current Good Manufacturing Practice requirements.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart C – Hazard Analysis and Risk-based Preventive Controls

- 507.31 Food safety plan
- 507.33 Hazard analysis
- 507.34 Preventive controls
- 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control
- 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).
- 507.38 Recall plan
- 507.39 Preventive control management components
- 507.40 Monitoring
- 507.42 Corrective actions and corrections
- 507.45 Verification
- 507.47 Validation
- 507.49 Verification of implementation and effectiveness
- 507.50 Reanalysis
- 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food
- 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor
- 507.55 Implementation records required for this subpart



1-36

Slide 35

Most of the remaining curriculum will focus on subpart C, the hazard analysis, and risk-based preventive controls requirements. There are many requirements to this subpart, and they will be discussed in detail in the coming chapters.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart D – Withdrawal of a Qualified Facility Exemption

- 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.
- 507.62 Issuance of an order to withdraw a qualified facility exemption
- 507.65 Contents of an order to withdraw a qualified facility exemption
- 507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption
- 507.69 Procedure for submitting an appeal
- 507.71 Procedure for requesting an informal hearing
- 507.73 Requirements applicable to an informal hearing
- 507.75 Presiding officer for an appeal and for an informal hearing
- 507.77 Timeframe for issuing a decision on an appeal
- 507.80 Revocation of an order to withdraw a qualified facility exemption.
- 507.83 Final agency action
- 507.85 Reinstatement of a qualified facility exemption that was withdrawn



Slide 36

Subpart D explains the circumstances that may lead to FDA's withdrawal of a facility's *Qualified Facility* exemption to subparts C and E, the process of the withdrawal, and processes and procedures that a facility must undergo to have its *Qualified Facility* status reinstated.

The FDA may withdraw a *Qualified Facility* exemption if: 1) there is an active investigation of a foodborne illness outbreak directly linked to the *Qualified Facility*; or 2) FDA determines it is necessary to protect the public human or animal health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the *Qualified Facility* that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.


Generally, a *Qualified Facility* has an exemption from the requirements of subpart C and E and is instead subject to other requirements for a *Qualified Facility* found in 21 CFR 507.7. However, if a problem occurs, FDA has the ability to withdraw the exemption.

Because of the limited application of this subpart, it will not be covered in this curriculum. Please refer to appendix 1 for additional information on subpart D.

21 CFR Part 507 –
Preventive Controls for Animal Food

Subpart E – Supply-Chain Program

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


1-38

Slide 37

Subpart E highlights the Supply-Chain Program and its requirements. That subpart will be discussed in depth during Chapter 9.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart F – Requirements Applying to Records That Must be Established and Maintained

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



Small entities may want to refer to the FDA **Guidance for Industry: What You Need to Know About Establishment, Maintenance, and Availability of Records — Small Entity Compliance Guide**. It can be found at:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/UCM391440.pdf>.

Slide 38

Subpart F is referenced throughout the regulation and will also be referenced throughout the training. Subpart F provides the requirements applying to records that must be established and maintained to be in compliance with the *Preventive Controls for Animal Food* rule. Sections in subpart F will be addressed more specifically in the next few slides.

21 CFR 507.200 Records subject to the requirements of this subpart

- (a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.
- (b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.
- (c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.
- (d) The requirements of § 507.206 apply only to the written food safety plan.
- (e) The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to records required by § 507.7.



Slide 39

All records that must be maintained under part 507 are subject to the requirements within subpart F, including those training records for *Qualified Individuals* as previously mentioned at the beginning of Chapter 1. Records required by Part 507 must be made promptly available for official review and copying upon oral or written request.

If required records are obtained by FDA (for example, during an inspection or investigation), they are subject to the records disclosure requirements of 21 CFR part 20. (21 CFR 507.200(b)). This means FDA may release them in response to a Freedom of Information Act request, subject to the requirements and exemptions of part 20. Some exemptions that might apply to records subject to this rule protect: trade secrets and confidential commercial or financial information, and information that would constitute a clearly unwarranted invasion of personal privacy of the individuals involved (for example, home addresses and telephone numbers, personal email addresses). FDA may redact or withhold records from a requestor if a record meets these, or other exemptions. For more information about Freedom of Information at FDA, see <http://www.fda.gov/RegulatoryInformation/FOI/ucm390370.htm>.

21 CFR 507.202

General requirements applying to records

- (a) Records must:
 - (1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
 - (2) Contain the actual values and observations obtained during verification activities;
 - (3) Be accurate, indelible, and legible;
 - (4) Be created concurrently with performance of the activity documented; and
 - (5) Be as detailed as necessary to provide history of work performed.

**Slide 40**

Records must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronically. They must contain actual values and observations obtained during monitoring, and, as appropriate, verification activities. They must be accurate, indelible which means they need to be in pen or an electronic form, and legible. The records must be created concurrently with performance of the activity documented and be sufficiently detailed to provide a history of work performed.

Although the records required to be established and maintained by a *Qualified Facility* are subject to subpart F, certain requirements specified in subpart F are not applicable since the requirements relate to provisions in subpart C. As such records established by a *Qualified Facility* do not need to: 1) contain actual values and observations obtained during monitoring, and, as appropriate, verification activities; 2) be created concurrently with performance of the activity documented; or 3) be as detailed as necessary to provide history of work performed

21 CFR 507.202

General requirements applying to records

- (b) All records must include:
 - (1) Information adequate to identify the plant or facility (e.g. the name, and when necessary, the location of the plant or facility);
 - (2) The date and, when appropriate, the time of the activity documented;
 - (3) The signature or initials of the person performing the activity;
 - (4) Where appropriate, the identity of the product and the lot code, if any.
- (c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.



Slide 41

The required records must include:

- Information adequate to identify the plant or facility, including its name and location when necessary.
- They must be dated, and time recorded when appropriate.
- Records must be signed with a signature or initial of the individual performing the activity.
- Where appropriate, the identity of the product or lot code must be included.

Again, as an exception, the records established by a *Qualified Facility* to meet the requirements in 21 CFR 507.7 do not need to conform to certain record requirements including the criteria specified on this slide (21 CFR 507.202(b)).

Records required under subpart F are exempt from Title 21 Part 11 requirements, so FDA's requirements for electronic records/electronic signatures do not apply.

What Records are Needed?

- Records must
 - Be kept as original records, true copies, or electronic record
 - Contain actual values and observations
 - Be accurate, indelible, and legible
 - Be created concurrently with performance of the activity
 - Be detailed as necessary
- Records must include
 - Information adequate to identify the plant or facility (name and location)
 - Date and, when appropriate, time of the activity
 - Signature or initials of the person performing the activity
 - The identity of the product and lot code, if any, when appropriate
- These records are exempt from 21 CFR 11 requirements.



Slide 42

Here is a quick summary that may be useful to refer to the requirements of records. Remember, these are the requirements whenever a section designates that records must meet subpart F requirements. Often, this means that current records in the facility may need to be updated to include locations for the facility name and address, as well as date, time, signature, and lot number, where appropriate.

**§ 507.206 Additional requirements applying to
the food safety plan**

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



Slide 43

The regulation specifically requires that the Food Safety Plan must be signed and dated by the owner, operator, or agent in charge of the facility upon the plan's completion and any modification. A preventive controls qualified individual's signature cannot substitute for the owner, operator, or agent in charge. They can be a co-signer of the document, but the requirement specifically states that the Food Safety Plan must be signed by the owner, operator, or agent in charge.

21 CFR 507.208**Requirements for record retention**

- (a)(1) All records required by this part must be maintained at the plant or facility for at least 2 years after the date they were prepared.
- (a)(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
- (b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g. because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the food safety plan (§ 507.45(b))).

**Slide 44**

All records must be retained at the animal food facility for at least 2 years after the date they were prepared. Some records may need to be retained even longer, such as 3 years of financial records for a *Qualified Facility*, or training records to document the training of *Qualified Individuals* for at least two years after an employee leaves.

Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued.

21 CFR 507.208

Requirements for record retention

- (c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.
- (d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.



Slide 45

Off-site record storage is permitted if records can be retrieved and provided onsite within 24 hours of request for official review, except that the Food Safety Plans must remain onsite. Electronic records are considered onsite if they are accessible from an onsite location. If the facility is closed for a prolonged period, the Food Safety Plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request.

21 CFR 507.212
Use of existing records

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



Slide 46

Many facilities have existing records (such as hazard analysis and critical control point (HACCP) plans) that may meet the requirements of 21 CFR 507, and it is acceptable for those records to be used to prevent duplication. These records may need to be supplemented, but the new and existing records may be combined or maintained and stored separately. The rule is flexible as to how the record is documented, as long as the requirements are met.

§ 507.215 Special requirements applicable to a written assurance

- Any written assurance required by this part must contain:
 - Effective date
 - Printed names and signatures of authorized officials
 - Applicable assurances
- Written assurances for when the facility is not required to implement a preventive control include
 - Acknowledgment that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions.
 - Provision that if the assurance is terminated, responsibility for compliance with the applicable provisions reverts to the manufacturer/processor on the date of termination.



Slide 47

Finally, any written assurance required by this part must contain the effective date, printed names and signatures of those individuals involved, and applicable assurances. The written assurances for when the facility is not required to implement a preventive control must include acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions and a provision that if the assurance is terminated, responsibility for the compliance with the applicable provisions reverts to the manufacturer or processor on the date of termination.

Regulation Overview Summary

The full regulation, 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, is in Appendix 1.

- Sections include
 - Subpart A – General Provisions
 - Subpart B – Current Good Manufacturing Practice
 - Subpart C – Hazard Analysis and Risk-based Preventive Controls
 - Subpart D – Withdrawal of a Qualified Facility Exemption
 - Subpart E – Supply-Chain Program
 - Subpart F – Requirements Applying to Records That Must be Established and Maintained

*Underlined subparts have been reviewed here. Other subparts will be reviewed in Ch. 2 to 10.



Slide 48

That ends the heavy regulatory text covered in this chapter. The full regulation can be found in Appendix 1. Subparts A, D, and F have been addressed in this chapter. The next chapter will focus on the requirements of subpart B: Current Good Manufacturing Practice requirements.

NOTES

PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

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.' FDA's current thinking on the subject is captured in their **Draft Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals.**

Slide 1

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

- Establishments solely 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)

CGMP Objectives

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



Slide 2

This chapter will address the following objectives:

- Describe the purpose of CGMP 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

Purpose of CGMP

- Considered by FDA to be "...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 contaminated with filth, or whereby it may have been rendered injurious to health" (Preamble, II: Legal Authority).
- Establishes baseline standards for the production of safe animal food and the creation of a successful Food Safety Plan.



Slide 3

FDA describes the purpose of CGMP 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 contaminated 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."

Other Programs Related to CGMP Regulations

- Other Animal Food Regulations with CGMP Regulations
 - 21 CFR Part 225 – Current Good Manufacturing Practice for Medicated Feeds
- Facility-Specific Prerequisite Programs
 - Employee Training
 - Facility Operations
 - Preventive Maintenance
 - Cleaning/Sanitation
 - Standard Operating Procedures
 - Quality Assurance
 - Animal Food Safety
 - HACCP
 - ISO
 - PAS 222



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 part 507.

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.

Part 507, Subpart B – Current Good Manufacturing Practice

- 21 CFR 507.14 - Personnel
- 21 CFR 507.17 - Plant and grounds
- 21 CFR 507.19 - Sanitation
- 21 CFR 507.20 - Water supply and plumbing
- 21 CFR 507.22 - Equipment and utensils
- 21 CFR 507.25 - Plant operations
- 21 CFR 507.27 - Holding and distribution
- 21 CFR 507.28 - Holding and distribution of human food by-products for use as animal food.



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*.

21 CFR 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.



The FDA GFI #235 uses the following example:

“Management expectations for personnel working in a livestock animal food plant might allow clothes that are dusty when working in the plant, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials. In contrast, a pet food plant concerned about microorganism contamination might require that personnel use protective clothing and dedicated plant footwear while working in the plant.”

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 when working in the facility, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials.

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

Example - Personnel

- Provide necessary facilities:
 - Lockers to store personal effects
 - Handwashing facilities as appropriate
 - Post appropriate signage to reinforce new practices
- Develop a personnel cleanliness protocol with training that specifies expectations regarding:
 - Handwashing
 - Wearing of jewelry
 - Carrying of cellular phones, tools



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.

Examples of objects from GFI # 235 that may fall into animal food, equipment, or containers include pens, sunglasses, gloves, tools, keys, pocket knives, and cell phones. Personnel should ensure items stored in pockets are secure or store them in designated areas.

21 CFR 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.*



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

21 CFR 507.17 – Plant and Grounds

- (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.



'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 and 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, the plant 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
 - When possible, ducts, fixtures, and pipes should not be located over animal food or animal food-contact surfaces. Condensation can be controlled by using drip pans to divert water away from animal food, or pipe insulation to prevent sweating. (source GFI #235)
- 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

Example – Plant and Grounds

- Existing facilities likely do not need to be redesigned or reconstructed, but compliance with requirements is necessary.
- Example: Provide acceptable lighting with shatter-resistant glass above storage or production areas.



FSPCA
2-10

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.

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.

21 CFR 507.17 – Plant and Grounds

- *(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.*



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

Example – Plant and Grounds

- Must protect animal food stored outdoors in bulk by any effective means when necessary or appropriate



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.

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 to a more permanent storage location. Depending upon the length of storage and other conditions, the outdoor pile may need to be protected by various means when necessary or appropriate. 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.
- Control the area around the animal food to eliminate pest harborage, perhaps by mowing vegetation, removing trash and junk piles, and preventing standing water.
- Keep bulk piles away from the eaves of buildings where birds or other pests could roost and serve as a source of contamination.
- Check bulk animal food on a regular basis for product condition and have a pest control plan, specifying monitoring locations and frequency.

Management would ultimately be responsible for determining the necessary and appropriate precautions needed to address potential contamination from the environment and/or pests.

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

21 CFR 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.*



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.

Example – Sanitation

- Minimize potential sources of environmental contamination by adequate cleaning and, when necessary, sanitizing procedures.
 - Notably, appropriate sanitation practices vary within different industry segments.



FSPCA
2-14

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.

21 CFR 507.19 – Sanitation

- (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 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.*

FSPCA
2-15

GFI #235 recommends leaving toxic materials in their original containers with the labeling intact when possible. If transferred to another container, the container should identify the contents. Instructions for proper use should be readily available for employees, such as safety data sheets (SDS). Toxic materials should be stored as recommended by their manufacturer, particularly those that are sensitive to light or temperature.

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.

Example – Sanitation

- Examples of toxic materials: fertilizers, cleaning compounds, treated seeds, and pesticides
- Toxic materials must be stored separately from materials intended for animal food and where animal food is manufactured, processed, packed, or stored.



FSPCA
2-16

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, the toxic chemical 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.

21 CFR 507.19 – Sanitation

- *(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.*



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.

21 CFR 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.*



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 these 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

Adequate Water

- Water must be:
 - Adequate for operation, from adequate source
 - Provides sufficient temperature and water volume to support facility operations
 - Safe for intended use if it contacts animal food, animal food contact surfaces, or animal food packaging material
 - Should be free of contaminants that could adulterate the animal food
 - Reused water is acceptable if it does not increase the contamination of the animal food



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 defined in 21 CFR 507.3, 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 to demonstrate that the facility determined the water source is adequate and safe for its intended use.

21 CFR 507.20 – Water supply and plumbing

- (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 floor 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.*



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

21 CFR 507.20 – Water supply and plumbing

- *(c) Sewage and liquid disposal waste must be disposed of through an adequate 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.*



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 located 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 arrangements may be needed 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.

Example – Water supply and plumbing

- If water temperature must reach a specific parameter for sanitation purposes, it should be measured.
- Adequate restroom facilities are required, and sewage/waste water must be conveyed so as to not cause animal food adulteration.
- Additional handwashing facilities may be necessary depending on the operation.



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. According to GFI #235, 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.

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/guidance/regulation/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.

21 CFR 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;*



Examples of utensils include buckets, shovels, and scoops. They need to be maintained so that their parts and pieces do not fall off and contaminate animal food.

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.

21 CFR 507.22 – Equipment and Utensils

- (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-monitoring device.*



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/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.

Example – Equipment and Utensils

- Equipment, storage, conveyors, and utensils, such as brooms, shovels, scoops, must be in good physical condition so they are not a source of contamination themselves.
- Select equipment and utensils made of materials that will withstand the conditions of use in the facility.



FSPCA
2-25

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 readily corrode or deteriorate under wet conditions.

21 CFR 507.22 – Equipment and Utensils

- (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 gasses 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.*



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.

Example – Equipment and Utensils

- Thermometers used with freezers and cold storage, or other instruments to maintain specific environmental conditions associated with preventing animal food hazards, must be effective.
- Compressed air should be used cautiously when cleaning so as to protect against the contamination of animal food.



FSPCA
2-27

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.

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.

21 CFR 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 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;*



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

21 CFR 507.25 – Plant operations

- (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.



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

21 CFR 507.25 – Plant operations

- (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.*



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. In addition:

- 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

21 CFR 507.25 – Plant operations

- (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 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.

Note – Inbound Ingredient Evaluation

- Preamble points:
 - Weather can be considered when evaluating raw materials susceptible to mycotoxin contamination.
 - Not every load of grain needs to be tested as long as evaluation results in the facility using ingredients in a manner that does not result in harm to humans or animals.
 - Visual examination of ingredients or shipping containers is acceptable, with emphasis on observing any unusual residues that may contaminate the animal food.



FSPCA
2-32

Slide 32

Some specific points raised for inbound ingredient evaluation in the preamble to the *Preventive Controls for Animal Food* rule include:

- 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, every load of grain is not required to 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.

21 CFR 507.25 – Plant operations

- *(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;*



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.

21 CFR 507.25 – Plant operations

- (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-progress 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;



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 a_w . 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.

21 CFR 507.25 – Plant operations

- (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.



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 a_w 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.

Example – Plant operations

- Conduct appropriate evaluations to ensure inbound materials are safe
 - Raw materials must be evaluated for suitability, and shipping containers inspected to verify adulteration has not occurred.
- Hold materials in a safe manner
 - Flushes, rework, and rejected feed must be identified and utilized or disposed of appropriately.
 - Work-in-progress and rework must be protected from contamination and growth of biological hazards.
- Manufacture in a way to ensure safety
 - Reliance on water activity or pH to prevent growth of biological hazards must be monitored.



FSPCA
2-36

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
- Checking incoming temperatures for refrigerated or frozen ingredients

The CGMP requirements also stipulate 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 to the final 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, such as being able to identify bulk bin or silo contents using an electronic monitoring system. 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.

21 CFR 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.*



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, and holding animal food for distribution so that it does not become contaminated by sources such as trash.

According to the GFI #235, some factors to consider when developing practices to protect animal food against contamination during holding can include:

- Identification of animal food so it is not mistaken as trash
- Proximity of the animal food to potential sources of contamination, such as trash, waste, and rework
- Accessibility of clearly marked trash receptacles

21 CFR 507.27 – Holding and Distribution

- (b) *The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food 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.*



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

When an animal food is ready for distribution, 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.

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- (a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:
 - (1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
 - (2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
 - (3) During holding, human food by-products for use as animal food must be accurately identified.



Because the human food by-products for use as animal food addressed here 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 is 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 between intended animal food and trash.

Slide 39

21 CFR 507.28 provides requirements for holding and distribution of human food by-products for use as animal food.

Examples of human food by-products that are used as animal food from GFI #235, include:

- Wheat middlings generated in processing wheat for flour
- Grain products (e.g. hulls, bran, and germ) from other grain processing operations
- Peels, rinds, pumace, pulp, culls, or other similar material generated from processing fruits or vegetables for human consumption,
- Human food such as potato chips, cookies, bread, pastry products, and pasta that is not adulterated and is safe for use as animal food, but is not acceptable as human food for quality reasons such as the wrong size, shape, color, or texture.

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 from the requirements in 21 CFR 507.27, 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.

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- *(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.*
- *(c) Shipping containers (e.g. totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as 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 human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.*



'Labeling' may mean the physical container that holds bulk animal food during distribution is labeled or that the individual packages of animal food have labeling affixed to the packages. 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 when the by-product is distributed.

Example – Holding and Distribution

- For holding and distribution of ingredients, human food by-products for use in animal food, or animal food, it is required that:
 - Containers are appropriate to protect against contamination.



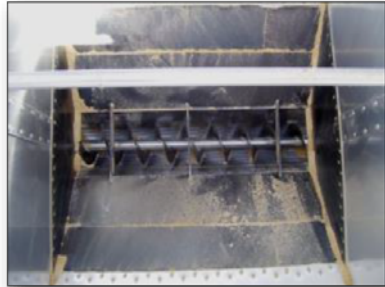
Slide 41

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 of 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.

Example – Holding and Distribution

- For holding and distribution of ingredients, human food by-products for use in animal food, or animal food, it is required that:
 - Containers and bulk vehicles must be examined prior to use.



FSPCA
2-42

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, is in appropriate sanitary condition, regardless if the loading facility arranged for the conveyance or not.

CGMP Regulations Summary

- CGMP regulations provide the foundation necessary for production of safe animal food.
- CGMP regulations are required, and most are managed outside the Food Safety Plan.
- It is important to understand the specific requirements, and train as necessary in order that all individuals involved understand and effectively implement CGMP regulations.



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 activities emphasized by the CGMP requirements are those that can be observed within a facility and do not require specific documentation. However, recordkeeping is recognized as a general good business practice. In addition, 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.

NOTES

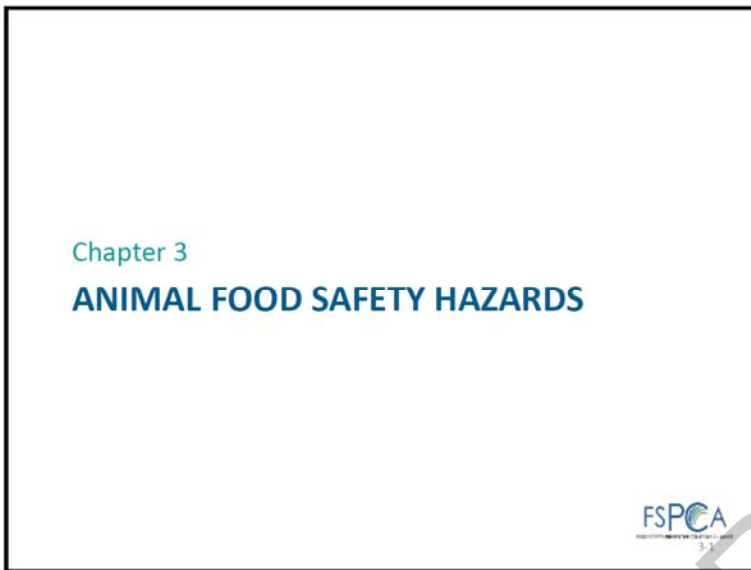
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

CHAPTER 3. Animal Food Safety Hazards



Slide 1

This chapter will focus on types of hazards potentially associated with animal food and will provide background information that will be useful during the hazard identification process.

Animal Food Safety Hazards Objectives

In this module, you will develop:

- An understanding of what to consider during hazard analysis.
- The ability to recognize that hazards vary among animal species.
- An awareness of potential biological, chemical (including radiological), and physical hazards in animal food.



Slide 2

In this module, participants will develop: 1) an understanding of what should be considered during hazard analysis; 2) the ability to recognize that hazards vary among animal species; 3) and an awareness of potential biological, chemical (including radiological), and physical hazards in animal food.

21 CFR 507.33 – Hazard Analysis

- (a)(1) *You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and*
- (2) *The hazard analysis must be written regardless of its outcome.*



Note that when the *Preventive Controls for Animal Food* rule refers to 'you,' as it does in this section, the 'you' is the owner, operator, or agent in charge of the facility.

The owner, operator, or agent in charge of the facility is responsible for the hazard analysis described in this section. However, the owner, operator, or agent in charge of the facility may designate the responsibility of conducting the hazard analysis to the *Preventive Controls Qualified Individual*, as long as they recognize that the ultimate responsibility rests with the owner, operator, or agent in charge.

Slide 3

The Hazard Analysis section begins on page 56345 of Appendix 1. Specifically, *You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and the hazard analysis must be written.*

The majority of the hazard analysis requirements, including additional hazard evaluation components, will be covered in Chapter 5: Hazard Analysis and Preventive Controls Determination. For this chapter, the focus is on the fact that a hazard analysis must be conducted to identify known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at a facility. This first step of a hazard analysis narrows down an entire universe of hazards to those that are known or reasonably foreseeable.

21 CFR 507.33 – Hazard Analysis

- (b) *The hazard analysis must consider:*
 - (1) *Known or reasonably foreseeable hazards that include:*
 - (i) *Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;*
 - (ii) *Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and*
 - (iii) *Physical hazards (such as stones, glass, and metal fragments); and*



While these 3 categories of hazards are utilized throughout this chapter, there are additional definitions associated with biological hazards that can be found in 21 CFR 507.3. These include *pathogen, microorganism, and environmental pathogen.*

Slide 4

Hazard analysis involves the identification and further evaluation of hazards. Potential hazards in animal food will be classified into three broad categories: biological hazards, chemical hazards, and physical hazards. The regulation provides examples for each of these categories, but this is not an exhaustive list of all known or reasonably foreseeable hazards. The regulation specifically draws out that some hazards are more relevant in one species compared to another. A key takeaway is that when considering hazards, it is important to consider the manufacturing environment and the species for which the animal food is intended.

21 CFR 507.33 – Hazard Analysis

- (2) *Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:*
 - (i) *The hazard occurs naturally;*
 - (ii) *The hazard may be unintentionally introduced; or*
 - (iii) *The hazard may be intentionally introduced for purposes of economic gain.*



Slide 5

Finally, the hazard analysis must consider *known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons: 1) the hazard occurs naturally; 2) the hazard may be unintentionally introduced; or 3) the hazard may be intentionally introduced for purposes of economic gain.*

21 CFR 507.3 – Definition: “Hazard”

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



A key component of this definition is that a hazard may cause *illness or injury to humans or animals*. A consideration for severity is part of the hazard analysis process that will be described later, but both the impact on animal and human health must be considered at this stage.

Slide 6

Because this is a chapter about hazards, it is appropriate to introduce the definition of hazard found in 21 CFR 507.3, which can be found on page 56338 of Appendix 1. A hazard means *any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals*.

A key part of this definition is that it specifies an agent can be a hazard if it causes illness or injury in humans **or** animals. The hazard analysis must consider those hazards that may potentially impact human health due to their role in handling animal food or the edible products (meat, milk, eggs) from animals consuming the animal food. However, the hazard analysis must also consider the impact on the animal itself. For this reason, some hazards for animal food may be different than those for human food. While human food is only required to consider hazards for a single species (humans), the hazard analysis for animal food often requires the consideration for multiple animal species and humans who may be impacted.

21 CFR 507.3 – Definition:

“Known or Reasonably Foreseeable Hazard”


- A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

**Slide 7**

The definition for a *known or reasonably foreseeable hazard* is found on page 56339 of Appendix 1. This is a further classification of a hazard. Distinction between this term and the term *hazard* is key in the hazard identification and evaluation process that is discussed throughout this chapter. A *known or reasonably foreseeable hazard* is “a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.” The critical component of the definition is the known or potential association with the facility or the animal food.

21 CFR 507.3 – Definition:
“Hazard Requiring a Preventive Control”

- A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility’s food safety system.


3-8

Slide 8

Once a facility has identified a *known or reasonably foreseeable hazard*, the next step of the hazard analysis process is to determine if the hazard is a *hazard requiring a preventive control*. The first key component of this long definition is that the determination is to be made by “a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food...” This fits the definition of a Preventive Controls Qualified Individual.

Next, the definition calls out that the establishment of preventive controls is dependent upon “an assessment of the severity of the illness or injury to humans **or** animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.” Possible methods to assess severity and probability are described in chapter 5.

The definition goes on to clarify that the hazard can be controlled by either one or multiple preventive controls, which either “significantly minimize or prevent the hazard in animal food.”

Finally, the definition states that a *hazard requiring a preventive control* has necessary “components to manage those controls.” There is flexibility as the management components are as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility’s food safety system.

21 CFR 507.3 – Definition:
“Preventive Controls”

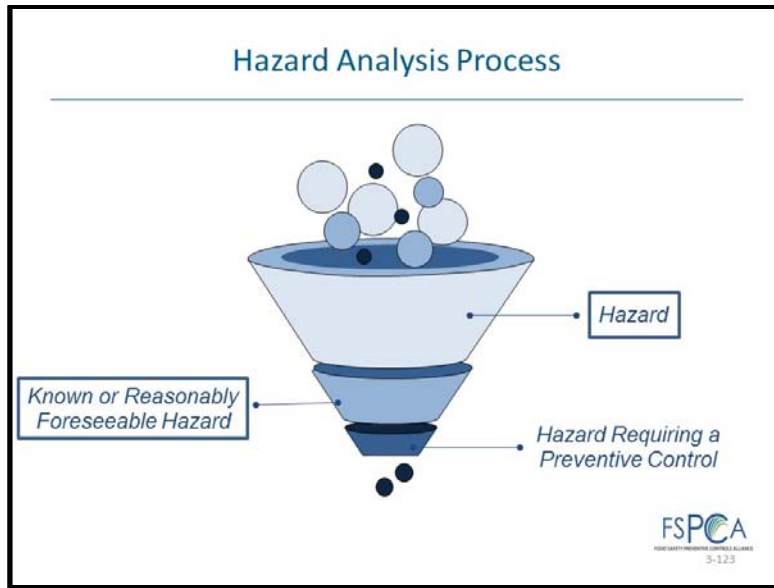
- *Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.*



Slide 9

Preventive Controls are those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls can be categorized by the method employed to control the hazard: process controls (which mitigate hazards through an action during the process itself), sanitation controls (which mitigate hazards through active sanitation procedures to prevent cross-contamination), supply-chain-applied controls (which requires control of the hazard at the supplier level), or other controls (which control hazards through different means other than those previously specified). There will be more discussion of the types of preventive controls and their required management components in the next chapters.



Slide 10

As can be seen, there are many definitions for the various categories of hazards. This slide graphically depicts the hazard analysis process. The process starts with the most general category of hazards – those that have the potential to cause illness or injury to humans or animals. Then, the hazard category gets narrowed to those hazards that are known or reasonably foreseeable based on the types of animal food the facility manufactures, processes, packs or holds. Finally, the combination of severity and probability are considered when further refining hazards to those that require a preventive control. Hazards requiring a preventive control are those that must be significantly minimized or prevented with preventive controls.

This chapter will focus on hazards, and identifying which hazards are known or reasonably foreseeable in different types of animal food. The determination if they require a preventive control will be described fully in Chapter 5: Hazard Analysis and Preventive Controls Determination.

Hazard Does Not Necessarily Refer To:

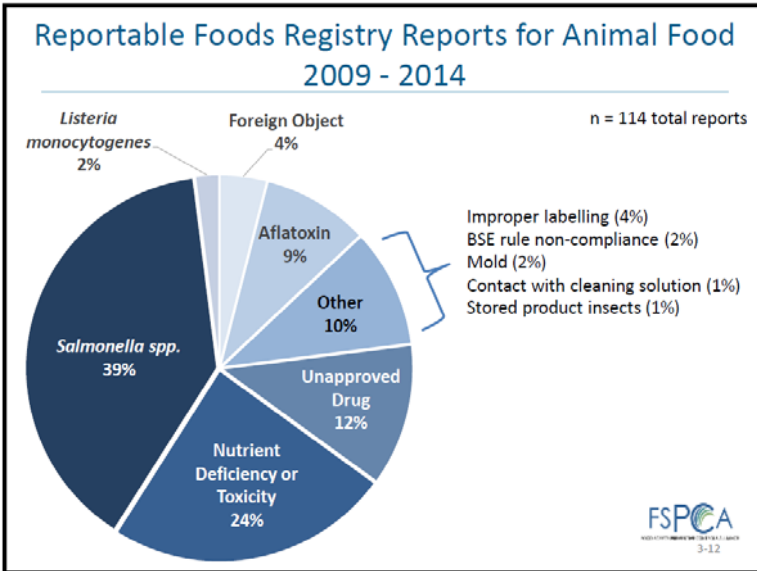
- Violations of regulatory standards not directly related to food safety or covered by other regulations, such as
 - Labeling requirements
 - Economic fraud
- Undesirable situations not involving a hazard, such as product quality



Slide 11

As participants reflect on the hazard definition, it is important to understand that there are some animal food regulations that will not be discussed thoroughly in this curriculum because they are not likely to lead to food safety concerns. For example, there are specific labeling requirements for both medicated and non-medicated animal foods. These labeling requirements must be met in accordance with various rules, but in some cases, mislabeling or economic fraud is not considered a food safety concern. One such instance is if an ingredient manufacturer intentionally mislabels chicken by-product meal as duck meal because the two have similar nutrient profiles and duck meal commands a higher price. In this case, the mislabeling is economic fraud and is a regulatory violation of other rules, but does not necessarily constitute a hazard within the *Preventive Controls for Animal Food* rule. Conversely, mislabeling beef meal as pork meal may be considered a hazard if it is sold to a ruminant feeder who then feeds it to beef cattle in violation of the Bovine Spongiform Encephalopathy (BSE) rule.

Furthermore, there are occasional examples where undesirable situations are not necessarily hazards, such as poor product quality. For example, a pelleted goat food manufacturer may not properly cool pellets after thermal processing and prior to packaging. As a result, the product may exhibit poor pellet quality, but would not cause potential illness or injury to humans or animals, and would therefore not meet the definition of a hazard.



Slide 12

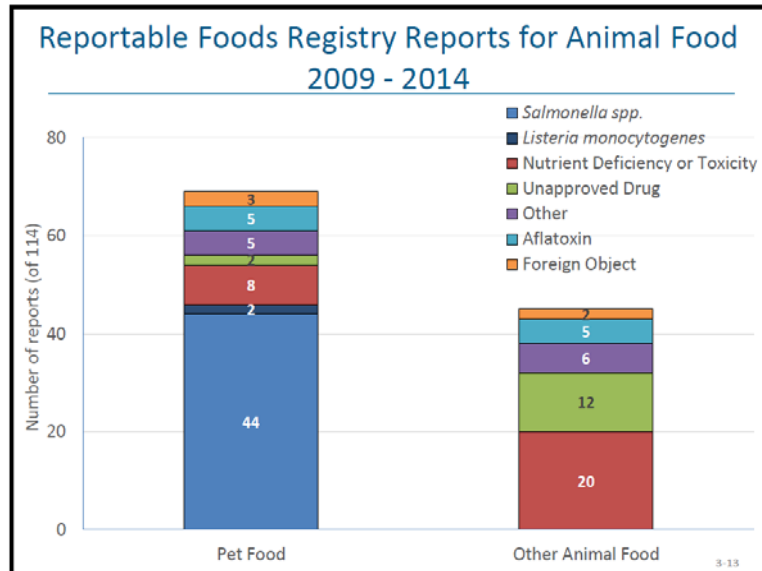
When beginning the hazard analysis process, it is helpful to understand the types of hazards that have previously been associated with the types of animal food that are manufactured, processed, packed, or held at your facility. A good resource for this data is the Reportable Food Registry, or RFR. This is an electronic portal to which facilities required to register as a food facility with FDA must report if there is a reasonable probability that the use of, or exposure to, animal food will cause **Serious Adverse Health Consequences or Death to Humans or Animals**. These are often abbreviated as SAHCODHA hazards. Since its inception, there have been five annual reports published at the time of this curriculum's development: 2009-2010, 2010-2011, 2011-2012, 2012-2013, and 2013-2014, which can be found on the FDA website.

There were a total of 114 RFR reports for animal food from 2009-2014. Thirty-nine percent of all RFR reports for animal food during this time were due to *Salmonella* contamination. Other major reporting categories included nutrient deficiencies or toxicities (24%), unapproved drug contamination (12%), aflatoxin (9%), and foreign objects, such as metal or glass (4%). *Listeria monocytogenes* contamination also resulted in 2% of RFR reports. All the remaining RFR reports, such as improper labeling, non-compliance with BSE regulations, mold, cleaning solution contamination, or pest activity, totaled 10%. An understanding of the total scope of RFR reports is helpful to prioritize focus during hazard analysis.

The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is a reasonable probability that a food will cause serious adverse health consequences or death. The RFR applies to all FDA-regulated categories of human and animal food, except dietary supplements and infant formula.

Who Should Use the Reportable Food Registry?

Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.



The Reportable Food Registry (RFR) is one example of a type of reference that may be used to identify known or reasonably foreseeable hazards in different types of animal food, but other resources are likely needed. These resources will be described in Chapter 5.

Slide 13

This slide shows the same data, but broken down by the numerical occurrence of RFR reports associated with either pet food or other animal food. As participants can see, all the *Salmonella* spp. and *Listeria monocytogenes* RFR reports were associated with pet food, and microbial hazards were responsible for 67% of all RFR reports in pet food. Part of the reason for the greater proportion of *Salmonella* spp. reports in pet food is its potential implications on human health, which is described more fully later in the chapter. Conversely, either nutrient deficiencies or toxicities or unapproved drug contamination accounted for 70% of the other animal food hazards. The RFR reports can be evaluated by breaking down those hazards associated with specific animal species. For example, sheep food was associated with six total RFR reports during these years. Of those, five were due to copper toxicity and one to unapproved drug contamination.

While the RFR annual reports are useful, there are many other resources to consider when identifying hazards. For example, *Listeria monocytogenes* was not reported in the RFR reports until the 2013-2014 annual report, which was published in May 2016. However scientific research reported *Listeria monocytogenes* in raw, fresh, and frozen pet food as early as 2014 and a firm recalled selected lots of pet food in May 2014 for the hazard. Other resources, such as scientific literature, industry whitepapers, and guidance for industry are available and are important to consider. Those resources and others are discussed in more detail during the hazard identification and evaluation section of Chapter 5: Hazard Analysis and Preventive Controls Determination.

Example Hazards in Animal Foods

- **Biological hazards:**
 - Bovine Spongiform Encephalopathy
 - *Salmonella* spp.
 - *Listeria monocytogenes*
- **Chemical hazards:**
 - Mycotoxins
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
- **Physical hazards:**
 - Stones
 - Glass
 - Metal



This is a general list of example hazards. Some of the hazards on this list are not associated with all types of animal food, while there are other hazards that may be *known or reasonably foreseeable hazards* for a type of animal food or a facility that are not listed. This is not meant to be a comprehensive list. Each facility must conduct a hazard analysis specific to that facility.

Many of hazards discussed in this chapter are referenced directly in the *Preventive Controls for Animal Food* rule or the Preamble due to their association with animal food in the past.

Slide 14


The *Preventive Controls for Animal Food* rule discusses the three categories of hazards and examples of each. This list of hazard examples in animal foods is based on the examples in the rule, RFR reports, scientific literature, and other resources.

Specifically, biological hazards can include agents such as Bovine Spongiform Encephalopathy (BSE) or undesirable microorganisms, such as *Salmonella* spp. and *Listeria monocytogenes*. Chemical hazards can include mycotoxins, pesticides, process-related or industrial chemicals, drug carryover, and nutrient deficiencies and toxicities. Finally, physical hazards can include stones, glass, and metal.

In the next section, each of these hazard categories are discussed more fully, starting with the biological hazards.

Biological Hazards in Animal Foods

- Bovine Spongiform Encephalopathy (BSE) is a type of transmissible spongiform encephalopathy (TSE) that is a degenerative, neurological disease.
 - Can be transmitted via animal food
 - Long incubation period
- Rules established by FDA in 1997 and 2008:
 - Prohibit feeding of most mammalian proteins to ruminants
 - Prohibit feeding of high risk cattle materials to all animals
 - Prevent contamination during transport and manufacturing practices
- The US is recognized as having a negligible BSE risk



Sources: 21 CFR 589.2000 and 21 CFR 589.2001
World Organisation for Animal Health Resolution No. 20

FSPCA
3-15

Slide 15

Bovine Spongiform Encephalopathy (BSE) is a type of transmissible spongiform encephalopathy (TSE) that has occurred in US cattle. Other TSEs, such as Scrapie in sheep or transmissible mink encephalopathy also exist. BSE can be transmitted through animal food, as was observed in the late 1980s and early 1990s in the United Kingdom through the use of rendered bovine proteins in cattle feed. Incubation periods for the disease can be months to several years.

To control BSE, the FDA published 21 CFR 589.2000 in 1997 that prohibits the use of most mammalian protein in animal food intended for ruminant animals, such as cattle, sheep, and goats. These rules were strengthened in 2008, when FDA published 21 CFR 589.2001 prohibiting the use of specified risk material, such as brains and spinal cords from cattle older than 30 months of age, in all animal food. The rules also contain measures to prevent contamination during manufacturing or transportation.

Due to the implementation of these rules and limited BSE occurrence, the World Organisation for Animal Health characterized the United States of America as having a negligible BSE risk in 2016.

Biological Hazards in Animal Foods

- According to the FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals:
 - *Salmonella* spp.
 - Can cause salmonellosis when the pathogen is consumed by humans.
 - Animal foods that are contaminated with *Salmonella* are higher risk for causing illness if they come in direct contact with humans
 - *Salmonella*-contaminated animal food can cause illness in animals that consume the food.
 - Depends on the serotype



Source: FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

3-16

Slide 16

Salmonella is a bacterium that may cause salmonellosis when the pathogen is consumed. It thrives in warm, humid environments, but can survive in low-moisture situations. Because of this, dehydrated or freeze-dried ingredients or finished foods may be contaminated when they are rehydrated.

In humans, symptoms of salmonellosis include nausea, vomiting, abdominal cramps, minimal diarrhea, fever, and headache. Certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems, are particularly susceptible to acquiring salmonellosis from pet food, and may experience more severe symptoms. *Salmonella* also has widespread occurrence in animals, especially poultry and swine. Animals may be infected either clinically, where they show symptoms similar to those in humans, or asymptotically but are still at a potential for shedding and spreading the bacteria.

The role of *Salmonella* in animal food as a potential hazard to both humans and animals is described in the FDA Compliance Policy Guide Sec. 690.800: *Salmonella* in Food for Animals. It describes that certain animal foods, such as pet food, pose a high risk to human health when they are contaminated with *Salmonella* because they are direct human contact foods. This means that there is a high likelihood that humans will come in direct contact with these foods, such as through direct ingestion by people or from hands or utensils that are contaminated when feeding pets.

Salmonella-contaminated animal food can cause illness in animals that consume that food. Whether *Salmonella* causes illness in an animal depends on the serotype. A serotype is a further classification of a broad species of bacteria. For example, there are more than 2,500 different serotypes of *Salmonella* that differ from one another by small variations in structure and function. Those serotypes that cause disease in a particular species are referred to as pathogenic for that animal species.

FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals contains further background and examples of pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these animal foods.

There are additional definitions that are associated with biological hazards that can be found in 21 CFR 507.3.

Microorganisms: means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Undesirable microorganisms: includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

Biological Hazards in Animal Foods

- *Salmonella* spp.
 - Pet food is adulterated when contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process
 - Animal food is adulterated when contaminated with a *Salmonella* serotype that is considered to be pathogenic to the animal intended to consume the animal food and the animal food will not subsequently undergo a commercial heat step or other commercial process



Source: FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

Slide 17

Salmonella serotype differentiation is important. FDA considers a pet food or a pet food ingredient to be adulterated when it is contaminated with any serotype of *Salmonella* and will not undergo a commercial heat step that will kill the *Salmonella*. This is partially because pet food is a direct human contact food.

Alternatively, FDA considers other animal food to be adulterated only when it is contaminated with a *Salmonella* serotype considered to be pathogenic to the animal species intended to consume the animal food. Unlike pet foods, the majority of food for other animals is not thermally-processed. When it is, the intent of the process is typically to improve nutrient availability to the animal or other quality aspects of the animal food by pelleting, extruding, or expanding the product. Thus, thermal processing in most foods for other animals is not intended as a *Salmonella* control step.

Biological Hazards in Animal Foods

- *Salmonella* spp.
 - Current examples of animal foods and the pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these foods:
 - Poultry food with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
 - Swine food with *Salmonella* Choleraesuis
 - Sheep food with *Salmonella* Abortusovis
 - Horse food with *Salmonella* Abortusequi
 - Dairy and beef food(s) with *Salmonella* Newport or *Salmonella* Dublin



Source: FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

Slide 18

The Compliance Policy Guide lists current examples of animal foods and the pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these animal foods. While these are currently the listed serotypes, FDA stipulates that all other *Salmonella* serotypes should be evaluated on a case-by-case basis.

Biological Hazards in Animal Foods

- *Listeria monocytogenes*
 - Recently identified in raw, fresh, and frozen pet food
 - Nemser et al., 2014
 - 196 raw dog and cat foods sampled
 - 16.3% of samples positive for *L. monocytogenes*



Depiction of a *L. monocytogenes*



For more information, refer to:
 Nemser SM, Doran T, Grabenstein M, McConnell T, McGrath T, Pamboukian R, Smith AC, Achen M, Danzeisen G, Kim S, Liu Y, Robeson S, Rosario G, McWilliams Wilson K, Reimschuessel R. Investigation of *Listeria*, *Salmonella*, and toxigenic *Escherichia coli* in various pet foods. *Foodborne Pathog Dis.* 2014 Sep;11(9):706-9.

Slide 19

L. monocytogenes is unique in that it can survive in both the presence and absence of oxygen. The bacteria can grow and proliferate in frozen and refrigerated environments. Listeriosis in animals may result in swelling of the brain, neurological-related circling, and late-term abortions.

The 2013-2014 annual RFR report was the first to identify *Listeria monocytogenes* presence in raw, fresh, and frozen pet foods. Since then, recalls associated with this undesirable microorganism have increased. Furthermore, a peer-reviewed research paper published in 2014 demonstrated that 16.3% of the 196 raw cat and dog foods sampled were positive for the pathogen. This recent addition of a biological hazard as a known or reasonably foreseeable hazard for some pet foods underscores that reanalysis of the hazard identification and evaluation may be necessary as new information becomes available.

Example Hazards in Animal Foods

- Biological hazards:
 - Bovine Spongiform Encephalopathy
 - *Salmonella* spp.
 - *Listeria monocytogenes*
- Chemical hazards:
 - Mycotoxins
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
- Physical hazards:
 - Stones
 - Glass
 - Metal



In most regions, radiological hazards are not likely to be hazards requiring a preventive control. When they are, the most common way these radionuclides are incorporated into animal food is through use of water that contains a radionuclide. Radiological hazards also may result from accidental contamination, such as contamination arising from accidental release from a nuclear facility or damage to a nuclear facility from a natural disaster.

The Preamble of the *Preventive Controls for Animal Food Rule* describes decomposition as “microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death.”

Slide 20

While biological hazards were most associated with pet foods, chemical hazards were responsible for majority of the RFR reports in other animal foods. Chemical hazards can include radiological hazards. This curriculum does not cover radiological hazards in depth because they are not likely to be known or reasonably foreseeable in most regions. More common chemical hazards include substances such as pesticides, drug carryover, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities. Specific hazards discussed here include mycotoxins, chemical contamination from pesticides and process-related or industrial chemicals, drug carryover, and nutrient deficiencies or toxicities. However, it should be recognized that chemical hazards can vary widely and certainly may extend to examples not discussed in this chapter.

Chemical Hazards in Animal Foods

- The presence of chemical hazards in animal foods may be:
 - **Naturally-occurring**
 - Mycotoxins
 - **Unintentionally-introduced**
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
 - **Intentionally-introduced for purposes of economic gain**
 - Melamine



Slide 21

The hazard analysis process must consider known or reasonably foreseeable hazards that may be present. Examples of hazards that are naturally occurring, unintentionally introduced, and intentionally introduced for purposes of economic gain are shown above. These reasons for introduction must be considered for all hazards, regardless if they are biological, chemical, or physical in nature.

Mycotoxins are an example of a hazard that occurs naturally and will be discussed in more detail in the next four slides.

Naturally-Occurring Chemical Hazards in Animal Foods

- Mycotoxins
 - Specific growing conditions (cool/wet or hot) in some grains encourage the growth of various mold species.
 - Some molds, such as aspergillus and fusarium, occasionally produce mycotoxins during specific environmental conditions.
 - Mycotoxins can cause serious illness in humans and animals at very low dosages.
 - Severity depends upon animal physiology, phase of production.



Source: Mycotoxins: Risks in Plant, Animal, and Human Systems. CAST Task Force Report 2003.

While molds and their growth are biological systems, any mycotoxins produced by those molds are considered to be chemical hazards.


Not all molds produce mycotoxins. Even molds that may potentially produce mycotoxins do not produce those toxins except under specific temporal conditions. Thus, molds are not considered biological hazards within this curriculum, while mycotoxins are considered chemical hazards.

Slide 22

Mycotoxins are naturally-occurring hazards that are a result of specific growing conditions encouraging mold growth in different grains. Some molds, such as aspergillus spp. and fusarium spp., occasionally produce mycotoxins during specific environmental conditions. While these molds may be present without producing mycotoxins, their growth and production of the toxin occurs with specific temporal conditions. For example, fusarium molds that produce zearalenone and deoxynivalenol are more likely to occur during cool, wet conditions, while aspergillus molds that produce aflatoxin are more likely to occur in hot environments. Mycotoxins can cause serious illness in humans and animals at very low dosages. The severity of illnesses depends upon the type of mycotoxin present and the animal's physiology. The types of illnesses that may result from these toxins are discussed next.

Naturally-Occurring Chemical Hazards in Animal Foods

- Mycotoxins
 - Aflatoxin
 - DON
 - Fumonisin
 - Ochratoxin A
 - T-2/HT-2
 - Zearalenone



Aspergillus mold on corn

FSPCA
NATIONAL FEED SAFETY PROMOTION CENTER
3-23

Slide 23

There are several different types of mycotoxins, and the severity of illnesses they cause may vary depending upon their concentration and the animal consuming the animal food. Common types of mycotoxins and the raw agricultural commodity they are most commonly found in:

- Aflatoxin is commonly found in peanuts, corn, wheat, cottonseed, and nuts.
- Deoxynivalenol, or DON, is sometimes called vomitoxin and is most commonly found in corn, wheat, barley, and oats.
- Fumonisin is most commonly found in corn, wheat, sorghum, barley, and oats.
- Ochratoxin A is most commonly found in wheat, barley, oats, corn, and dry beans.
- T-2, which rapidly metabolizes to HT-2, is found most commonly in barley, wheat, and oats.
- Zearalenone is commonly found in corn, wheat, barley, and rye.

Most recalls and RFR reports have been associated with aflatoxin due to its frequency of occurrence and severity of illness, which is why it is focused on the most during this chapter.

Naturally-Occurring Chemical Hazards in Animal Foods

- Mycotoxins
 - Aflatoxin (corn, peanut products)
 - Can be transmitted through milk, meat, and eggs to humans
 - Highly carcinogenic
 - In animals, causes mortality, decreased weight gain and egg/milk production

FDA Action Limits for Aflatoxin

Level	Ingredient	Animal
300 ppb	Corn or Peanut Products	Finishing Beef Cattle
300 ppb	Cotton Seed Meal	Beef Cattle, Swine, Poultry
200 ppb	Corn or Peanut Products	Finishing Swine (100 lb BW or greater)
100 ppb	Corn, Peanut Products, Other Animal Foods	Breeding Beef Cattle, Breeding Swine, Mature Poultry
20 ppb	Corn, Peanut Products, Other Animal Foods	Immature Animals and Others Not Listed



Source: FDA Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds

Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed contains information on levels of chemicals that are prohibited in certain foods. These levels are based on FDA's assessment of long term and short-term effects of consuming the specific chemical.

This slide depicts action levels for aflatoxin, but there are advisory and caution levels for other mycotoxins that can be found in FDA guidance or precautionary levels that may be found in scientific literature. Each facility should consider the mycotoxins that are relevant to the ingredients they utilize and the intended species. The facility should also consider that there may be additive effects of different types of mycotoxins.

Slide 24

Aflatoxins may cause different levels of illness within different animal species and within different production stages of the same species. Aflatoxin's implications in human health mark its severity. For example, aflatoxins may cause organ failure and mortality in some animal species, such as dogs and cats, while others may experience less severe symptoms, such as depressed milk production in dairy cows. However, aflatoxin can be transmitted from the animal food through milk, meat, and eggs. This is concerning because aflatoxin is one of the most potent naturally-occurring carcinogens known to man. The danger of this toxin to both human and animal health has resulted in the FDA setting levels for the toxin in different types of animal food. These levels are described in the FDA Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds. If an animal food has an aflatoxin concentration above that outlined for an intended animal species, the FDA may take regulatory action.

The animal's phase of production and physiology may affect how aflatoxin is metabolized, and thus its impact on illness or injury to humans or animals. Therefore, there are different action levels for different species and production phases. The specific levels from the Compliance Policy Guide are listed above. For example, the action level for corn and peanut products intended for finishing beef cattle is 300 parts per billion (ppb), while the action level for immature animals and other animals, such as dairy cattle and pets, is just 20 ppb.

Naturally-Occurring Chemical Hazards in Animal Foods

- Mycotoxins
 - Deoxynivalenol/DON/Vomitoxin
 - Vomiting, diarrhea, feed refusal, decreased milk production
 - Fumonisin
 - Feed refusal, ELEM (equine leukoencephalomalacia)
 - Ochratoxin A
 - Mortality, decreased weight gain, and poor egg production/quality
 - T-2/HT-2
 - Mortality, infertility
 - Zearalenone
 - Estrogenic effects in swine, embryonic death, inhibition of fetal development



Source: Mycotoxins: Risks in Plant, Animal, and Human Systems. CAST Task Force Report 2003.

FDA Guidance for Industry establishes limits and levels for deoxynivalenol and fumonisins in animal food. Other resources to help determine appropriate threshold levels for different species and physiological states of animals include the CAST Task Force Report referenced on the slide and *A Guide for Grain Elevators, Feed Manufacturers, Grain Processors and Exporters* from the National Grain and Feed Association.

Slide 25

There are also FDA advisory or guidance levels for other mycotoxins, but they are less stringent than those for aflatoxin. Still, those mycotoxins may have dramatic impacts on animal health, such as:

- Deoxynivalenol concentrations above threshold levels may result in vomiting, diarrhea, animal food refusal, and decreased milk production in animals.
- Horses are particularly susceptible to fumonisins, as they can lead to equine leukoencephalomalacia, or ELEM. Because horses cannot metabolize the toxin well, concentrations greater than 2 parts per million (ppm) in food for horses may cause drowsiness, blindness, circling, staggering, and death within 48 to 72 hours. Fumonisin can also cause animal food refusal.
- Ochratoxin A is known to result in mortality and decreased weight gain in many animals, as well as poor egg production and poor egg quality in layer chickens.
- T-2/HT-2 described earlier can lead to mortality and infertility in certain species.
- Zearalenone has been associated with estrogenic effects that lead to embryonic death and the inhibition of fetal growth, as well as infertility. These symptoms are most commonly observed in swine, but can occur in other species.

The type and concentration of a mycotoxin – as well as its interaction within each animal species – impact the likeliness for its consideration as a hazard. The hazard analysis must consider temporal conditions, particularly in the case for mycotoxins, as their presence may change due to geographical location and annual environmental conditions.

Chemical Hazards in Animal Foods

- The presence of chemical hazards in animal foods may be:
 - Naturally-occurring
 - Mycotoxins
 - Unintentionally-introduced
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
 - Intentionally-introduced for purposes of economic gain
 - Melamine



Slide 26

While mycotoxins are an example of chemical hazards that are naturally occurring, some hazards are unintentionally-introduced by humans or the manufacturing process. These include pesticides and process-related or industrial chemicals, drug carryover, and nutrient deficiencies or toxicities.

Unintentionally-Introduced Chemical Hazards in Animal Foods

- Pesticides and other chemical residues
 - Polychlorinated biphenyls, dioxins, process-related chemicals, chlorinated pesticides
 - Found in the environment and accumulate in fat tissue
 - FDA pesticide surveillance suggests very few animal food samples have pesticide levels that exceed permitted levels
 - Of 420 samples collected in FY 2013, 11 (2.6%) contained violative pesticide levels that exceeded an EPA tolerance or FDA action level (FDA Pesticide Monitoring Program Fiscal year 2013 Pesticide Report)



Compliance Policy Guide Sec. 575.100 Pesticide Residues in Food and Feed contains information for the maximum amount of a pesticide residue that may be present in raw agricultural commodities and animal food.

The 11 violative pesticide levels were found in 3 domestic samples and 8 imported samples. Three were in whole and ground grains/seeds, 7 in plant by-products, and 1 in pet food/treats. There were 0 violative levels in mixed livestock food rations, medicated livestock food rations, hay and silage, animal by-products, or other animal food ingredients.

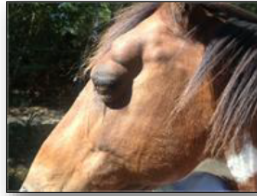
For all animal food samples, the most frequently found pesticides were ethoxyquin and malathion.

Slide 27

Pesticides may be introduced by direct contamination from facility pesticide programs, from contaminated grains, or from contamination of animal-based products due to tissue accumulation. Dioxins and process-related chemicals, such as chlorinated pesticides, are toxic industrial pollutants that may be found in the environment and accumulate in fat tissue. While these are all concerns, FDA pesticide surveillance suggests that a very small percentage of animal food have pesticide levels that exceed permitted levels. For example, of 420 animal food samples collected in fiscal year 2013, eleven contained violative pesticide levels that exceeded an EPA tolerance or FDA action level (FDA Pesticide Monitoring Program Fiscal year 2013 Pesticide Report).

Unintentionally-Introduced Chemical Hazards in Animal Foods

- Drug carryover
 - Monensin poisoning in horses
 - Drug approved for use in cattle and poultry food
 - Horses are extremely sensitive (2-3 mg/kg of body weight = death)
 - No antidote



A horse with monensin poisoning.
Note the edema around eye sockets.

Slide 28

Drug carryover is also a chemical hazard that is usually unintentionally introduced. All medicated animal foods must be manufactured and distributed in accordance with the Current Good Manufacturing Requirements that are found in 21 CFR Part 225. An example of a drug carryover hazard is monensin poisoning in horses. Monensin sodium is an animal drug approved for use in cattle and poultry. However, there have been instances of monensin contamination in food for horses, where it is very toxic with 2 to 3 mg per kg of body weight likely resulting in death. Early stages of monensin poisoning in horses include elevated heart rate, muscle wasting, and edema, or swelling, around the eyes. Because monensin sodium is so toxic to horses, particular care must be used when a facility manufactures food for horses and animal food containing monensin sodium. This may include procedures to minimize the carryover of monensin from one batch of animal food to the next, such as the use of sequencing or flushing procedures.

Unintentionally Introduced Chemical Hazards in Animal Foods

- Nutrient Deficiencies or Toxicities
 - Unlike human foods, animal food is typically intended to be fed as a sole source of nutrients
 - Some animals have particularly sensitive nutrient requirements, especially vitamins and minerals
 - Inadequate thiamine in cats
 - Excessive vitamin D in dogs
 - Excessive copper in sheep
 - Some animal food manufacturing processes may impact the stability of sensitive nutrients, especially vitamins



The nutrient deficiencies or toxicities used in this chapter are those listed directly in the *Preventive Controls for Animal Food* rule as examples. These nutrient deficiencies and toxicities have caused animal illness in the past.

Slide 29

Other unintentionally-introduced chemical hazards may include nutrient deficiencies or toxicities. This is a hazard category that is unique to animal food because nutrient deficiencies or toxicities are a greater risk in animals than humans.

Consider this example: humans may reach their nutrient requirements through a variety of foods consumed throughout the day. For example, a person may choose to eat a serving of fruit, protein (eggs or bacon), and carbohydrate (toast) for breakfast, a salad full of nutritious vegetables and protein (chicken) for lunch, and have a dinner including a serving of protein (beef), carbohydrate (potatoes), dairy (glass of milk), and healthy fat (cheese).

Meanwhile, a single bag of animal food may be the single source of nutrients for an animal over a number of days or weeks. Therefore, it is essential that the diet be wholesome and safe – but also meet the animal's nutrient requirements.

Some animals have particularly sensitive nutrient requirements, especially to vitamins and minerals. For example, common nutrient deficiencies or toxicities that will be discussed are inadequate thiamine in cats, excessive vitamin D in dogs, and excessive copper in food for sheep. In addition to the animal's sensitivity to the nutrient, some animal food manufacturing processes may impact the stability of sensitive nutrients, such as vitamins, and lead to nutrient deficiencies.

Unintentionally Introduced Chemical Hazards in Animal Foods

- Inadequate thiamine in cat food
 - Thiamine is destroyed rapidly when subjected to heat and water.
 - Up to 90% of thiamine can be destroyed during the retort process in canning (DeNoya, 2015).
 - Thiamine is used as to maintain normal body processes in animals. Cats have a very high requirement, so short-term deficiency has substantial implications.
 - Ventriflexion/curled neck, seizure, death



Spinal curvature changes
from ventriflexion caused
by thiamine deficiency



Slide 30

Thiamine, sometimes referred to as vitamin B1, is a vitamin that is considered an essential nutrient for many animal species. Essential nutrients are ones that cannot be produced by the body and that must be supplied to an animal at a minimum level to maintain healthy bodily functions. Thiamine is an essential nutrient for cats.

Thiamine has been demonstrated to be rapidly destroyed when subjected to heat and water. These are environmental conditions common to the commercial processes for canned cat food production, and up to 90% of thiamine may be destroyed during the retort process of manufacturing canned cat food.

Thiamine deficiency in cats typically manifests itself as ventriflexion, or a curled neck as shown in the picture, followed by seizure and death. Careful maintenance and monitoring of thermal processing parameters are necessary to maintain maximum thiamine activity in cat food.

Unintentionally Introduced Chemical Hazards in Animal Foods

- Excessive vitamin D in dog food
 - The gut absorbs vitamin D in ratio with Ca
 - Excessive vitamin D can cause hypercalcemia (American Veterinary Medical Association, 2010)
 - May lead to calcification of smooth muscle, kidney failure, cardiovascular and nervous system disorders



Mineralization of a kidney due to hypercalcemia.

FSPCA
3-31

It is accepted that many nutrients, particularly many vitamins and minerals, are very difficult to analyze consistently. The Association of American Feed Control Officials (AAFCO) Official Publication lists acceptable analytical methods and range of analytical variation for various nutrients and drugs.

Slide 31

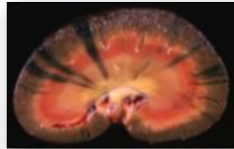
Although some essential nutrients must be fed at a minimum level for proper body function, some essential nutrients can be toxic to animals when fed at high levels. Having too much of a vitamin can be a hazard as well. Excessive vitamin D has been recognized as a potential hazard in dog food. Because the digestive tract absorbs vitamin D in proportion to the quantity of calcium, over-consumption of vitamin D by dogs causes excessive Ca absorption. This ultimately may lead to hypercalcemia, or hardening, of smooth muscle. Further impacts may include kidney failure and disorders of the cardiovascular and nervous system.

Unintentionally Introduced Chemical Hazards in Animal Foods

- Excessive copper in food for sheep
 - Copper is a required nutrient, but also may be toxic
 - Sheep are particularly sensitive to excessive copper
 - High copper levels cause oxidation of hemoglobin
 - Rapid, sudden death with shiny, blue kidneys



Normal kidney



Diseased kidney due to
excessive copper

FSPCA
3-32

Slide 32

Copper is required, but also potentially toxic, for all animal species. Because molybdenum is responsible for clearing copper from the liver, an overconsumption of copper in ratio to molybdenum may lead to copper toxicity and oxidation of hemoglobin. Copper toxicity can be both chronic and acute. This means that the accumulation of the mineral in the liver can cause toxicity if lower, but still toxic, levels are fed over many days or weeks. However, rapid, sudden death can occur from very high doses in a matter of hours. The picture in the slide shows two kidneys, one that is healthy, and one that is shiny and blue in color due to the oxidized hemoglobin that is characteristic of copper toxicity.

While all species may be impacted by copper toxicity, sheep are particularly sensitive to excessive copper because they have inherently lower molybdenum concentrations compared to other species. A typical sheep diet of 20% grain and 80% forage contains approximately 15 ppm copper with no added copper. When molybdenum levels are approximately 3 ppm, the tolerance level of copper for sheep is typically 20 to 25 ppm. Sheep fed diets with lower molybdenum levels would have a lower copper tolerance.

Chemical Hazards in Animal Foods

- The presence of chemical hazards in animal foods may be:
 - Naturally-occurring
 - Mycotoxins
 - Unintentionally-introduced
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
 - Intentionally-introduced for purposes of economic gain
 - Melamine



When considering hazards intentionally introduced for purposes of economic gain, a facility is not expected to consider all possible hazards that could fit this category. The preamble of the *Preventive Controls for Animal Food* rule states, "...the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past."

Slide 33

The focus to this point has been on chemical hazards that occur naturally or are unintentionally-introduced, however, there is the rare activity where a hazard is intentionally-introduced for purposes of economic gain. The most well-known example of this was the pet food recall in 2007 due to melamine contamination. This wide recall was due to a single overseas supplier that blended melamine into product labeled as wheat gluten to elevate the crude protein level of the ingredient. The ingredient was later purchased by pet food manufacturers. The combination of melamine with cyanuric acid in the ingredient resulted in more than 8,500 reported animal deaths. The original intent of adding the melamine was to falsify protein content. The unexpected result was that it created a major animal food safety concern. This was a clear incident when a supplier intentionally introduced a hazard for economic gain. Using visual inspection and verified suppliers may have prevented this hazard from entering the animal food supply.

Example Hazards in Animal Foods

- Biological hazards:
 - Bovine Spongiform Encephalopathy
 - *Salmonella* spp.
 - *Listeria monocytogenes*
- Chemical hazards:
 - Mycotoxins
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
- Physical hazards:
 - Stones
 - Glass
 - Metal

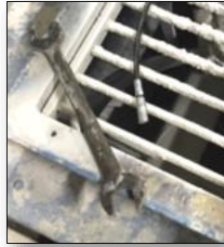


Slide 34

Now that biological and chemical hazards have been discussed, the focus will shift to the final category, physical hazards.

Physical Hazards in Animal Foods

- Stones
 - May be introduced with ingredients from fields
 - Choking, broken teeth
- Glass
 - May be introduced from broken lightbulbs or other glass in manufacturing facility
 - Cuts
- Metal
 - Punctures, cuts, broken teeth



Tool laying on top of hand-add grate

FSPCA
NATIONAL PET FOOD MANUFACTURING ASSOCIATION
3-35

Slide 35

Physical hazards, when present, may result in animal illness or injury. Typically, physical hazards in animal food are not associated with human illness or injury, but they are concerns for the animals consuming the food. These physical hazards can include items like stones, which may be introduced with ingredients from fields and cause choking or broken teeth in animals. Broken glass may be introduced from broken light bulbs or other glass in the ingredient or animal food manufacturing facility and result in cuts to the animal. Finally, metal may be introduced at a number of locations because nearly the whole animal food manufacturing process occurs using equipment with metal parts. Metal can result in several injuries to animals when consumed, such as cuts, broken teeth, or blockages.

Animal Food Safety Hazards Summary

- *Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.*
- Biological hazards in animal food may include BSE, *Salmonella* spp. and *Listeria monocytogenes*.
- Chemical hazards in animal food may include naturally-occurring hazards, such as mycotoxins, unintentionally-introduced, such as drug carryover or copper toxicity, and intentionally-introduced for purposes of economic gain, such as melamine.
- Physical hazards in animal food may include stones, glass, and metal.



Slide 36

That ends our discussion on animal food safety hazards. Remember that a hazard is defined as *any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals*. Biological hazards in animal food may include *Salmonella* spp. and *Listeria monocytogenes*. Chemical hazards may include naturally-occurring hazards, such as mycotoxins, unintentionally-introduced hazards, such as drug carryover and copper toxicity, and intentionally-introduced for purposes of economic gain, such as melamine. Finally, physical hazards in animal food may include stones, glass, and metal. Now that the participants have a fuller understanding of hazards associated with different types of animal foods, the next chapter will begin to describe the Food Safety Plan.

NOTES

PUBLIC VERSION

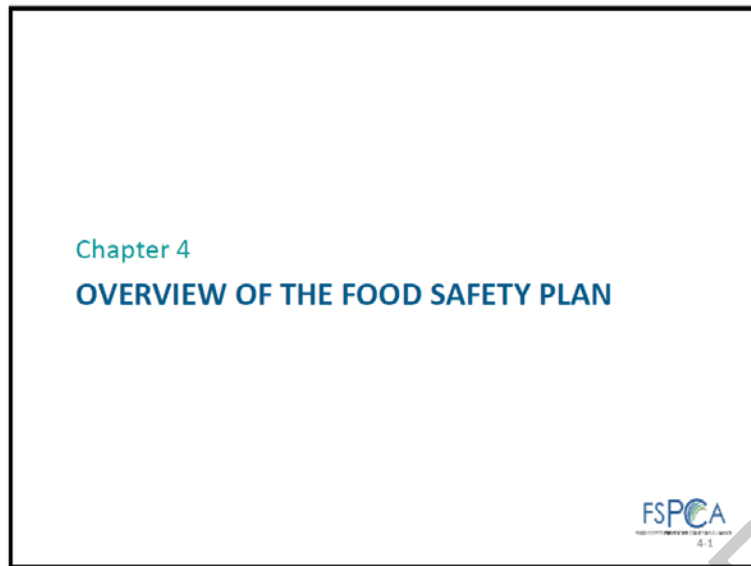
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

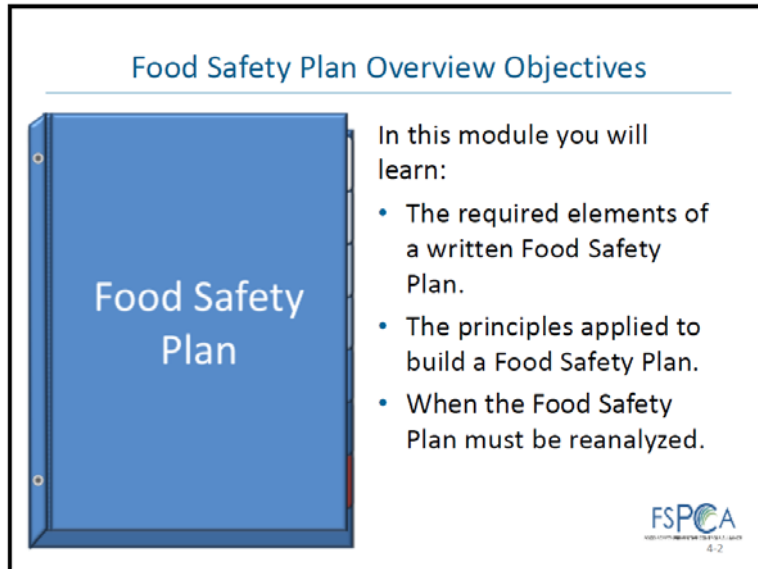
Blank Colored Insert-Back

CHAPTER 4. Overview of the Food Safety Plan



Slide 1

While Current Good Manufacturing Practices are a key component of ensuring a successful food safety system, the majority of this curriculum focuses on Subpart C of the *Preventive Controls for Animal Food* rule, which are the requirements for Hazard Analysis and Risk-Based Preventive Controls. The first requirement in subpart C is the requirement for a Food Safety Plan. This chapter will introduce the requirements associated with that plan.

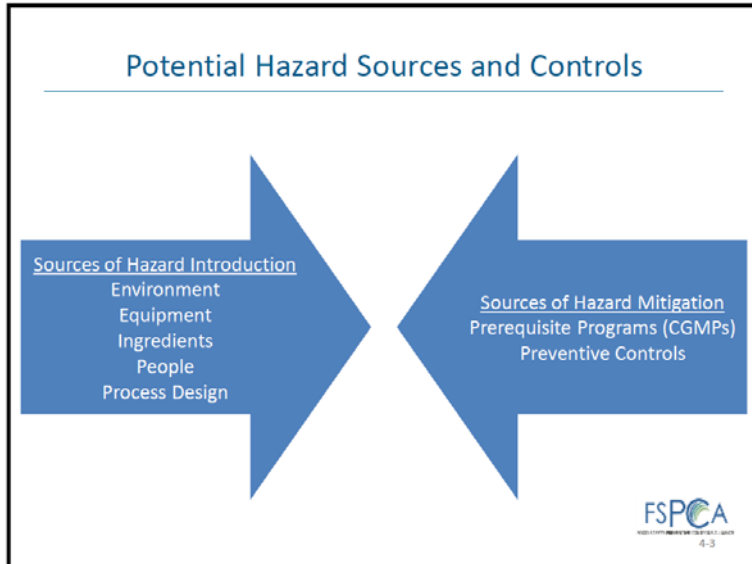


Slide 2

In this chapter, the required elements of a Food Safety Plan will be discussed, as well as the principles that must be applied to build the plan successfully.

The specific format of a Food Safety Plan is not defined by the regulation. Each facility can organize the required information in a manner that suits their systems, the needs of their employees, the needs of their customers, and the requirements of the regulation. The important thing is to have a plan that is easy to understand, implement and manage; that it is kept up to date; and that it is organized and accessible for inspection. The following is an example of how a Food Safety Plan might be set up, using a notebook. There is also no requirement that all components of a Food Safety Plan be contained in a single notebook – this curriculum just uses the picture as a model concept for development.

After the required elements of the Food Safety Plan are discussed, this chapter will describe when the Food Safety Plan must be reanalyzed.

**Slide 3**

Chapter 3 described the biological, chemical, and physical hazards typically associated with animal food. These hazards can come from a variety of sources, such as the environment (cross-contamination of pathogens on dust in the air), equipment (cross-contamination of pathogens on surfaces), ingredients (mycotoxins), people (human error), or process design (drug carryover). A facility's food safety system utilizes prerequisite programs, such as CGMPs, and preventive controls to prevent or significantly minimize hazards so they are no longer a food safety concern in animal food.

21 CFR 507.31 Food Safety Plan

- (a) You must prepare, or have prepared, and implement a written food safety plan.
- (b) One or more Preventive Controls Qualified Individuals must prepare, or oversee the preparation of, the food safety plan.



Note that when the *Preventive Controls for Animal Food* rule refers to 'you,' as it does in this section, the 'you' is the owner, operator, or agent in charge of the facility.

Slide 4

The *Preventive Controls for Animal Food* rule requires that a facility develop and implement a written Food Safety Plan. This plan may be written by the facility, or written for it by someone else. The *Preventive Controls Qualified Individual* (PCQI) for the facility is responsible for the Food Safety Plan's preparation, either directly or in an oversight capacity.

21 CFR 507.31 Food Safety Plan

- (c) *The written food safety plan must include:*
 - (1) *The written hazard analysis as required by § 507.33(a)(2);*
 - (2) *The written preventive controls as required by § 507.34(b);*
 - (3) *The written supply-chain program as required by subpart E of this part;*
 - (4) *The written recall plan as required by § 507.38(a)(1);*
 - (5) *The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);*
 - (6) *The written corrective action procedures as required by § 507.42(a)(1); and*
 - (7) *The written verification procedures as required by § 507.49(b).*
- (d) *The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.*



A reminder that Subpart F requires:

- Promptly making records available to FDA upon request
- Records kept as original records, true copies, or electronic records
- Contain actual values and observations
- Be accurate, indelible, and legible
- Be created concurrently with the activity being documented
- Be detailed as necessary
- Maintenance of records for 2 years after the date they were prepared

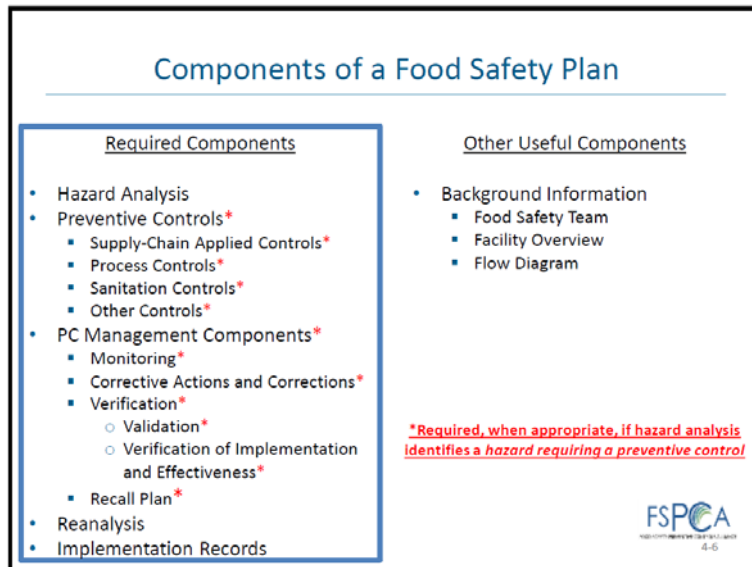
Records must include:

- Information adequate to identify the facility
- Date and time (if appropriate) of the time the activity was documented
- Signature or initials of person performing activity
- Identify of the product and lot code, where appropriate

Slide 5

There are 7 primary components that must be included in the written Food Safety Plan. These include the hazard analysis, preventive controls, supply-chain program, recall plan, procedures for monitoring the implementation of preventive controls, corrective action procedures, and verification procedures. However, each of these required components of the Food Safety Plan is listed as being “as required” by the specified section of the regulation. This can be confusing, because within the individual sections are specific circumstances or clarifications of when some of the required components, such as a written supply-chain program, are not required.

The Food Safety Plan is subject to the documentation requirements of Subpart F, which were summarized in Chapter 1 and highlighted in the participant’s note to the right of the slide.



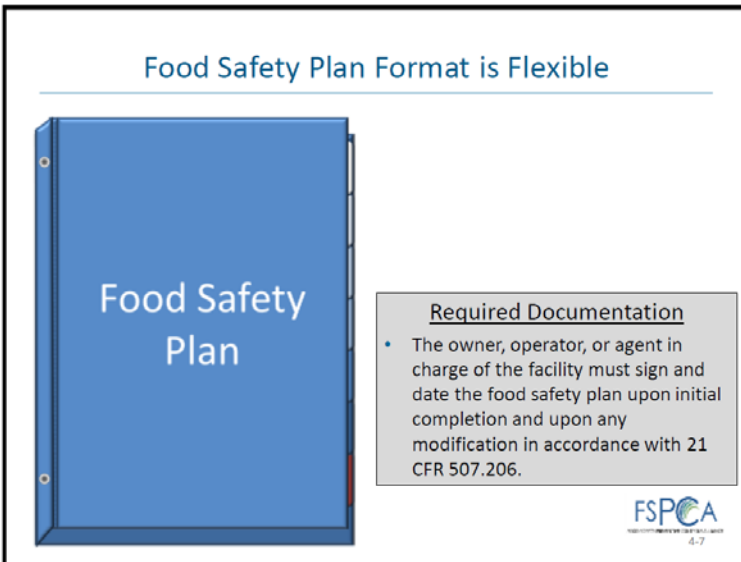
Some facilities may not have a *hazard requiring a preventive control*. In that instance, only the hazard analysis, reanalysis, and limited implementation record section are required.

If a facility has a *hazard requiring a preventive control*, it must have a preventive control, management components for that preventive control, and a recall plan. Not all management components are required for each type of preventive control. This is described thoroughly in later chapters, especially in Ch. 6.

Slide 6

This slide is quick visualization of the 7 components of the Food Safety Plan and when those components are required. Required components include: hazard analysis, preventive controls (including supply-chain-applied controls, process controls, sanitation controls, and/or other controls), components required to manage those controls (including monitoring, corrective actions and corrections, and verification activities such as validation and verification of implementation and effectiveness), a recall plan, and implementation records. Several of these components, which are denoted with an asterisk, are required as appropriate when a facility's hazard analysis determines there is a *hazard requiring a preventive control*.

While these are the required components, the Food Safety Plan should be thought of as a tool to help communicate the food safety system to employees, customers, and regulatory authorities. For this reason, it is recommended that additional background information be included in the Food Safety Plan. This background information can provide helpful context to other components of the Food Safety Plan. An industry good practice would be to include an overview of the facility, the members of the food safety team, description of the facility, and a diagram showing equipment within the facility. The next section describes a recommended way to organize this information so it can be used in a practical manner.

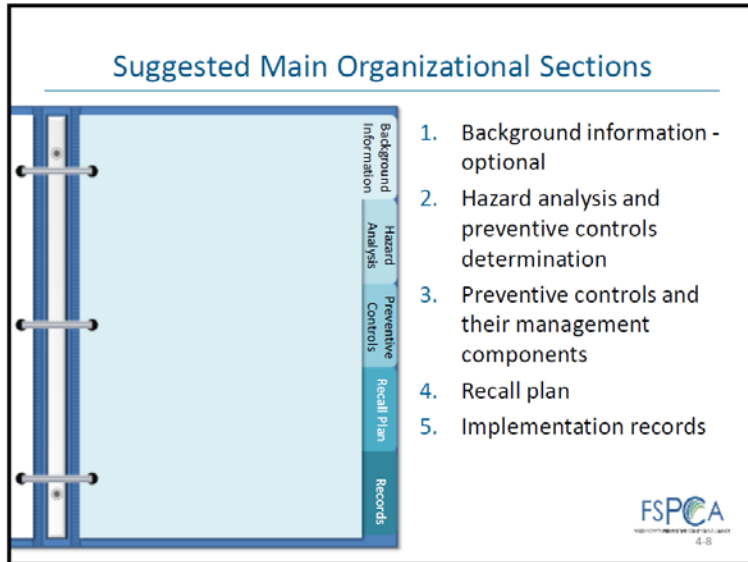


The signature of the owner, operator, or agent in charge of a facility is required because they are responsible for ensuring compliance with Subpart C.

Slide 7

There is flexibility in how to write and organize the Food Safety Plan. This chapter will describe one option for combining the components into a single binder with different tabbed dividers for each section. While the organization is flexible, some of the components that must be included are not. For that reason, the required documentation for each section is summarized in the gray box on the right side of the slide. Later chapters cover the specific requirements for this documentation, such as what monitoring records must be included.

The required documentation for this slide describes that there is a specific requirement for the Food Safety Plan itself. The owner, operator, or agent in charge of the facility must sign and date the Food Safety Plan upon initial completion and upon any modification. The facility has the option to store records offsite, as long as they are able to be retrieved within 24 hours. However, the Food Safety Plan must be located on the same site as the facility at all times. Electronic records, such as the Food Safety Plan, are considered onsite if they can be accessed from an onsite location.

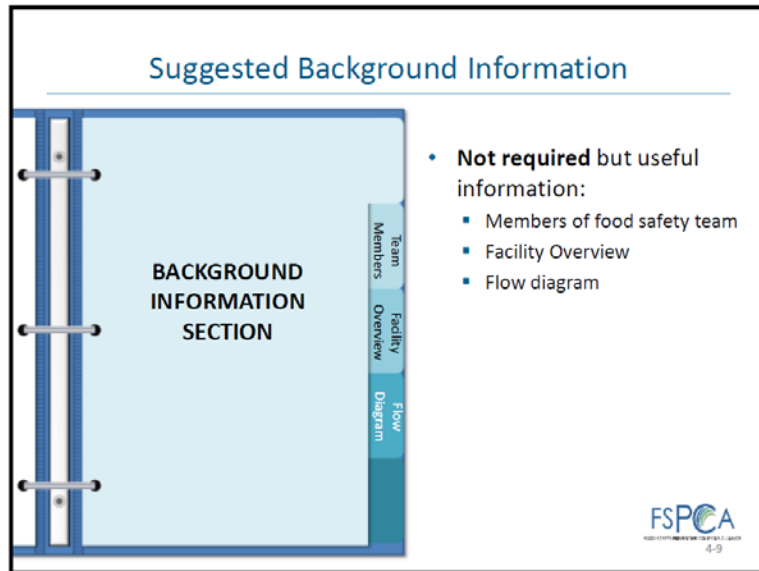


Slide 8

The example Food Safety Plan format described in this chapter has 5 primary section divisions:

1. Background information, which is optional, but suggested
2. Hazard analysis, including preventive controls determination
3. Preventive controls with the associated management components
4. Recall plan
5. Implementation records

As a reminder, if the result of a facility's hazard analysis is that there are *no hazards requiring a preventive control*, then the facility's Food Safety Plan will only be required to include the hazard analysis and implementation records.



Slide 9

The first section is the background information. Again, the *Preventive Controls for Animal Food* rule does not require this section, but it is recommended as a good industry practice. The inclusion of this chapter is helpful to communicate how the facility operates, which may be necessary when interacting with regulatory authorities, customers, and employees.

Useful information to include in this section are the members of the food safety team and their role within the facility, a description of the facility, and a flow diagram showing equipment within the facility. Depending upon the facility, other information may be included if deemed helpful, such as an overview of the facility and a description of how product flows through the process. If a facility has multiple products with different processes, it may be appropriate to cover each of the different processes within the description.

Optional: List Food Safety Team Members	
ABC Feed Mill	
Food Safety Team Members	
Name	Position
I.R. Charge*	Plant manager
F.S. Leader	Production supervisor
I.M. Quality	Quality supervisor
I.M. Fixer	Maintenance supervisor
*Preventive Controls Qualified Individual	



Slide 10

This is an example of a Food Safety Team member list that lists the individuals' names, and positions. The use of a food safety team is not a requirement. The PCQI may be the only one involved with development of the Food Safety Plan in some facilities. Other facilities will utilize a team of individuals across departments. In this example, the food safety team includes the plant manager, production supervisor, quality supervisor, and maintenance supervisor.

In the provided example, the plant manager is the facility's PCQI, and she attended an FSCPA-recognized course. Instead of attending the course, the PCQI also could have been qualified through another equivalent curriculum or through job experience. The plant manager and all the other members of the food safety team are qualified individuals because they have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to their duties. Copies of their training records in animal food safety and personnel hygiene are in the implementation records section of the Food Safety Plan for easy retrieval.

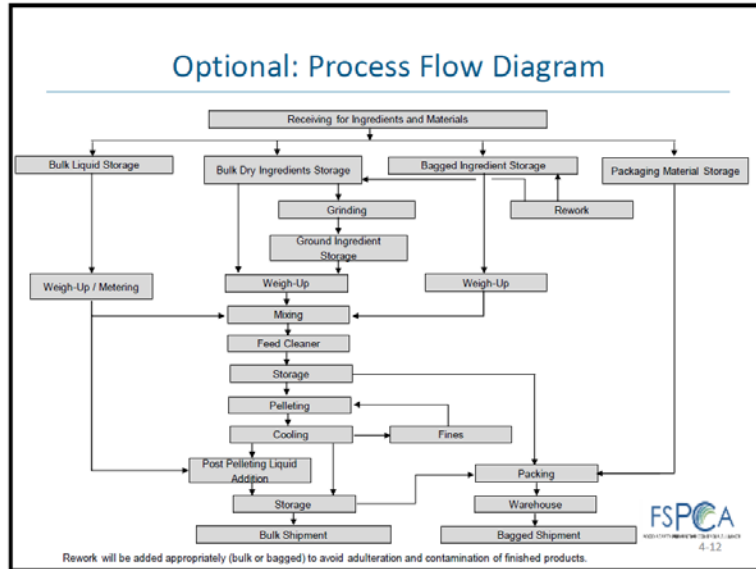
Optional: Facility Overview

- **Facility Description:** The facility was built in the 1960s and runs three shifts, 6 days per week. Approximate volume is between 350,000 and 500,000 tons annually.
- **Product Description:** Complete feeds for cattle, goats, poultry, sheep and swine at all ages. Feeds may be medicated or non-medicated. Feeds may be pelleted or mash.
- **Intended Use:** Feeds manufactured under this plan are to be fed as the sole ration to their intended species.
- **Animal Drugs:** Bacitracin methylene disalicylate, decoquinate, monensin, oxytetracycline, tylosin, virginiamycin

4-11

Slide 11

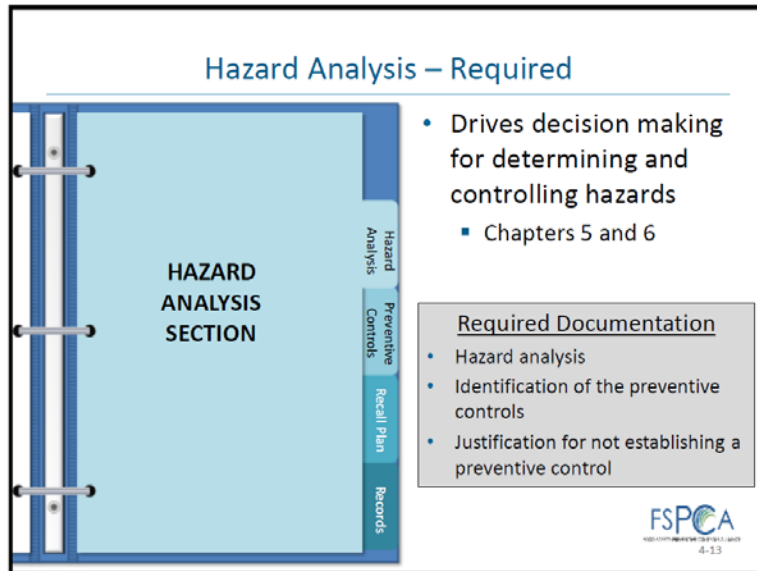
The next section is a facility overview, including a facility description, product description, intended use of the animal food, and medicated feed additives. In the case of ABC Feed Mill, the facility was built in the 1960s, operates 3 shifts per day, and runs 6 days per week. The approximate volume of feed manufactured is between 350,000 and 500,000 tons annually. The facility manufactures complete animal foods for cattle, goats, poultry, sheep, and swine at all ages. Animal food may be medicated or non-medicated and can be pelleted or mash. The animal foods are intended to be fed as a sole ration to their intended species, so there are no dry or liquid supplements manufactured in the facility. Finally, medicated feed additives are listed.



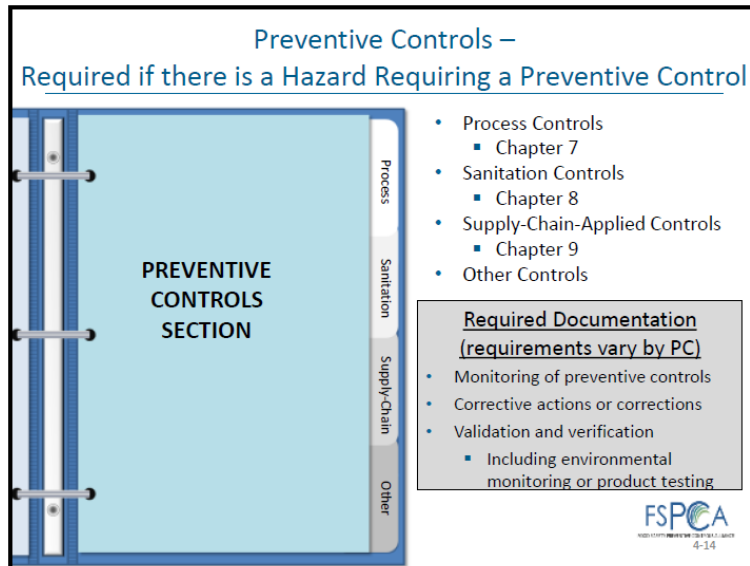
A relatively simple block flow diagram, such as the one in this slide, is very useful to quickly communicate how a facility manufactures, processes, packs, or holds animal food to employees, customers, and regulatory officials.

Slide 12

A process flow diagram is included next. This is not the blueprint of the facility, but instead is a block flow summarizing the ABC feed mill's manufacturing process from start to end. When flow diagrams are included, they can be as simple or complicated as desired to fit the needs of the facility. Flow diagrams are tools that can be used during the hazard identification process, so the flow diagrams should be accurate and as detailed as necessary.

**Slide 13**

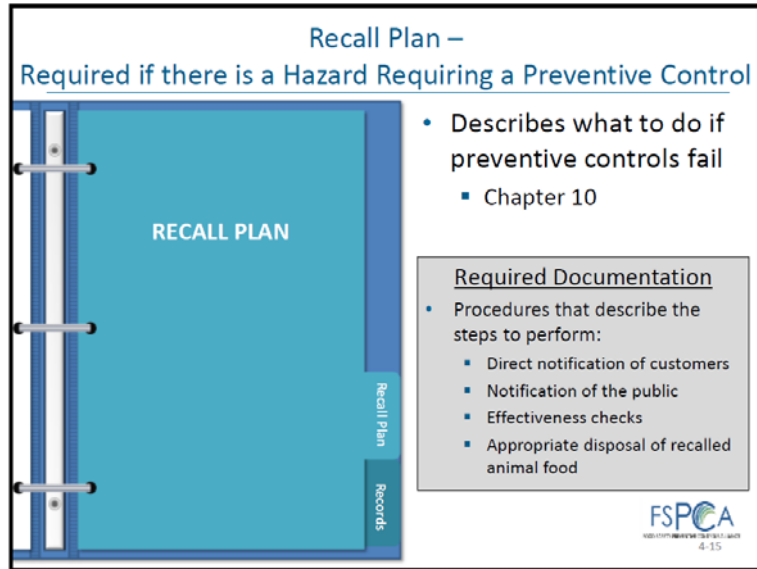
While the first segment of the Food Safety Plan was an optional good industry practice, the written hazard analysis is required. The hazard analysis is used to evaluate known or reasonably foreseeable hazards and to establish appropriate preventive controls for *hazards requiring a preventive control*. The hazard analysis and preventive controls determination process will be described more fully in Chapter 5. The hazard analysis, as well as the identification of preventive controls, is required to be included in the documentation for the Food Safety Plan. In addition, if a *known or reasonably foreseeable hazard* exists but was determined to not require a preventive control, justification for that determination must be included.



Slide 14

If there are any *hazards requiring a preventive control* identified in the hazard analysis, the preventive controls section is required in the Food Safety Plan. This curriculum covers controls by their potential types: Process Controls as discussed in Chapter 7, Sanitation Controls as described in Chapter 8, and Supply-Chain-Applied Controls as described in Chapter 9. There is also a category for Other Controls. Other controls are a type of preventive controls that do not fit the definition of process, sanitation, or supply-chain-applied controls. Other controls may include hygiene training or other current good manufacturing practices. This course will not cover other controls in-depth; however, they are a type of preventive control so the requirements that apply to preventive controls also apply to them.

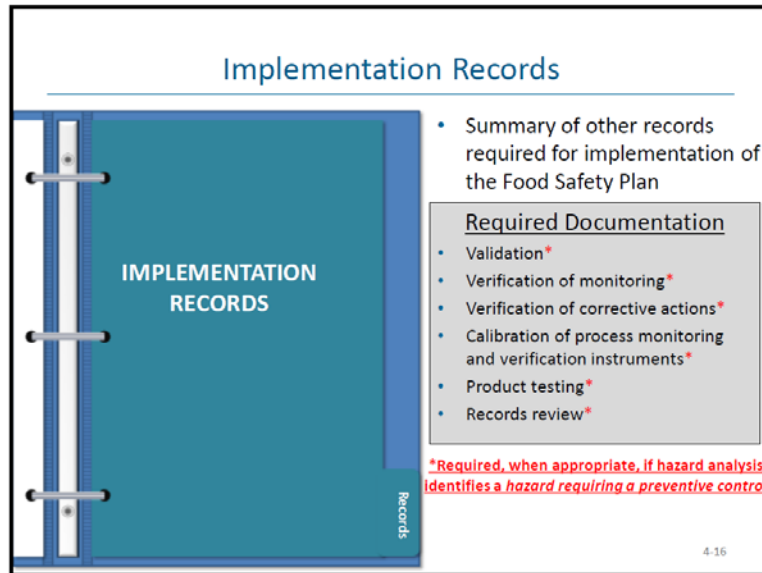
The preventive controls section of the Food Safety Plan has many requirements for documentation. These include monitoring, corrective actions or corrections, and validation and verification, which may include environmental monitoring or product testing records. The exact requirements will be described in each of the specific chapters.



A recall plan is only required if a facility has a *hazard requiring a preventive control*. However, it is a useful tool and all facilities should consider implementing such a plan, even if the facility is not required to implement preventive controls.

Slide 15

If a facility has identified a *hazard requiring a preventive control*, a recall plan for the animal food associated with the hazard is required. The recall plan describes the facility's course of action if a preventive control fails and contaminated product is distributed. The recall plan must include procedures for direct notification of customers, notification of the public, effectiveness checks to ensure the recall was successful in the facility retrieving the contaminated product from the marketplace, and appropriate disposal of the recalled animal food. These procedures are discussed in Chapter 10.



While implementation records for these Food Safety Plan components are required, they do not necessarily need to be part of the Food Safety Plan in this format. For example, this section may have examples of blank records and a listing of their storage location. The actual records may be maintained in various files or forms, including electronically.

Slide 16

Finally, the rule requires that certain records be kept and maintained by the facility. These do not have to be kept in one location. However, a section of implementation records in the Food Safety Plan may be helpful to organize all other records necessary for the Food Safety Plan. Required documentation includes validation of a preventive control, if required, verification of monitoring and corrective action, calibration of process monitoring and verification instruments, product testing, records review, and records that document applicable training for the PCQI and qualified auditor. While this example maintains copies of the training records within the binder itself, these records may be located in personnel files or other locations as long as they may be retrieved promptly upon request.

A list of all the records that are required to document implementation of the Food Safety Plan can be found in 21 CFR 507.55: Implementation Records. Refer to the *Preventive Controls for Animal* rule in Appendix 1 for further information. This section of the regulation does NOT establish any new record-keeping requirements. Instead, it provides just a quick-view reference for people to find a summary of all the records required under subpart C to demonstrate implementation of the Food Safety Plan.

21 CFR 507.50 Reanalysis

- (a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.
- (b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:
 - (1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
 - (2) Whenever you become aware of new information about potential hazards associated with the animal food;
 - (3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and
 - (4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.



Slide 17

In addition to the requirements of what must be documented within a Food Safety Plan, the *Preventive Controls for Animal Food* rule also describes the circumstances in which the Food Safety Plan must be reanalyzed. At a minimum, the Food Safety Plan must be reanalyzed at least every 3 years. The Food Safety Plan may need to be reanalyzed more frequently if: significant changes occur to the activities conducted at the facility, the facility becomes aware of new information about potential hazards associated with the type of animal food it makes, after an unanticipated food safety problem, or when the facility finds that a preventive control, combination of preventive controls, or the Food Safety Plan is ineffective.

21 CFR 507.50 Reanalysis

- (c) *You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified;*
 - (1) *Before any change in activities (including any change in preventive control) at the facility is operative; or,*
 - (2) *When necessary to demonstrate the control measures can be implemented as designed:*
 - (i) *Within 90 calendar days after production of the applicable animal food first begins; or*
 - (ii) *Within a reasonable timeframe, provided that the Preventive Controls Qualified Individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.*

4-18

Slide 18

If reanalysis determines a change in or addition of preventive controls is appropriate, the validation of those preventive controls must occur:

- 1) Before a change in activities at the facility is operative; or
- 2) When necessary to demonstrate the control measures can be implemented as designed:
 - a. Within 90 calendar days after production of the applicable animal food first begins; or
 - b. Within a reasonable timeframe, as long as the PCQI provides written justification for exceeding 90 calendar days.

The Preamble to the *Preventive Controls for Animal Food* rule gives more information regarding the requirement for when the validation of preventive controls must occur after reanalysis.

The Preamble states, "...if you decide to make a change, you should conduct a reanalysis before you make that change if there is potential for that change to create or increase a hazard; a reanalysis that results in changes to preventive controls should be completed and the preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, before changes in activities to produce animal food using a new preventive control are put into operation. However, we acknowledge that it may be necessary to produce product to demonstrate a revised preventive control can be implemented appropriately, and provide for an extended timeframe to make this assessment." See Preamble Response 378.

21 CFR 507.50 Reanalysis

- *(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.*
- *(e) A Preventive Controls Qualified Individual must perform (or oversee) the reanalysis.*
- *(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.*



Slide 19

The Food Safety Plan must also be revised if a significant change in activities conducted at the facility creates a reasonable potential for a new hazard or a significant increase occurred for a previously identified hazard. If no changes to the Food Safety Plan were deemed necessary during the reanalysis, that determination must be documented.

Any reanalysis of the Food Safety Plan is to be performed or overseen by the PCQI.

Although the reanalysis schedule is typically set by the facility, the facility may have to conduct a reanalysis if the FDA determines that reanalysis is required to respond to new hazards and developments in scientific understanding that may affect the process of producing a safe animal food.

Food Safety Plan Reanalysis

- A food safety system changes with time.
- Periodic reanalysis is needed to verify that the whole system works.
- Required:
 - At least every three (3) years
 - New information becomes available about potential hazards associated with the food
 - Corrective action and correction, when appropriate
 - Preventive control ineffective
 - Significant change in product or process



Examples of a significant change in product or process are listed here. There are other times when reanalysis is warranted more frequently, and those examples are given throughout the curriculum.

These include:

- New information becomes available about potential hazards associated with the food (Ch. 3)
- Unanticipated problem (Ch. 7)
- Preventive control is ineffective (Ch. 8)

Slide 20

To summarize, the food safety system changes over time, so periodic reanalysis of the Food Safety Plan is required to verify that the whole system, or components of the system, works. This reanalysis must occur at a minimum of every 3 years, but must occur more often if there is a significant change in the product or process, new information becomes available about potential hazards associated with the animal food, there is an unanticipated problem, or ineffectiveness of a preventive control. For example, if pathogens begin to become resistant to a specific type of sanitizer, it may be appropriate to reanalyze the sanitation controls in the Food Safety Plan.

Examples of significant changes that may warrant Food Safety Plan reanalysis include if there are changes in ingredients or suppliers, changes in product or process, new scientific information on hazards or control measures relevant to the product are found, or there are newly created distribution or consumer handling procedures. For example, repeated use of a correction suggests that the Food Safety Plan should be reanalyzed.

Reanalysis should include verifying that the hazard analysis is still accurate and that the required documentation is appropriate.

Food Safety Plan Overview Summary

- A written Food Safety Plan is required to include:
 - Hazard analysis
 - Implementation records
- If hazard analysis determines there is a *hazard requiring a preventive control*, the Food Safety Plan must also include:
 - Preventive controls and their management components
 - Recall plan
- The format is flexible to meet the needs of the facility.
- The Food Safety Plan must be reanalyzed at least every 3 years or more frequently, as appropriate.



Slide 21

In summary, the written Food Safety Plan must include the hazard analysis, preventive controls and their management components, a recall plan, and implementation records. It is also suggested that background information be included about the facility, people, products, and processes to help describe the facility's food safety system. The format of the Food Safety Plan is flexible to meet the needs of the organization, but the content of the Food Safety Plan and its associated records must meet the *Preventive Controls for Animal Food* rule's requirements. Finally, the Food Safety Plan must be analyzed at least every 3 years, but may need to be analyzed more frequently as required.

NOTES

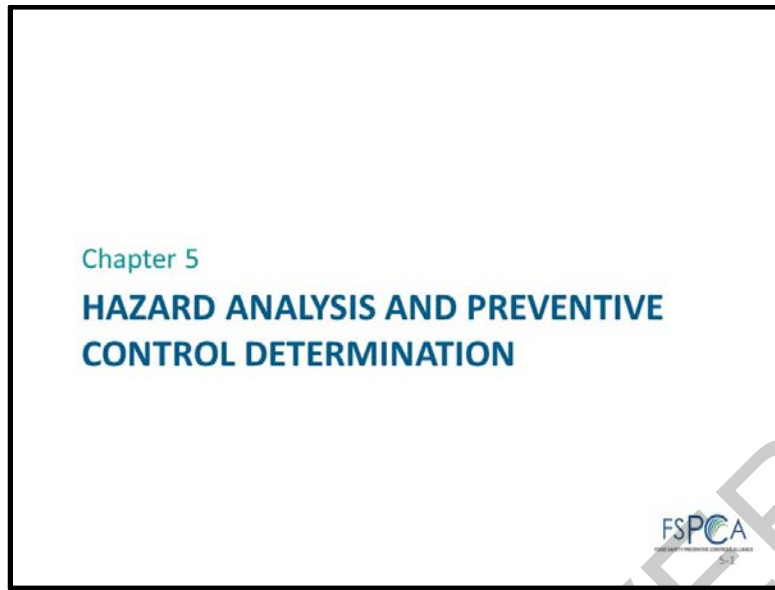
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

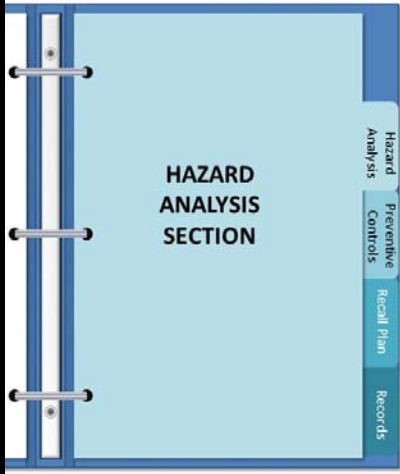
CHAPTER 5. Analysis and Preventive Controls Determination



Slide 1

While Chapter 3 discussed examples of hazards that may be considered by facilities, this chapter will help describe how to go through the hazard identification and evaluation process. This information is vital as a thorough hazard analysis is the foundation for the creation and implementation of a successful Food Safety Plan.

Hazard Analysis and Preventives Controls Determination Objectives



In this module, you will learn how to:

- Conduct a hazard analysis
- Determine hazards that require a preventive control
- Identify resources to help assess severity and probability of hazards

FSPCA
5-2

Slide 2

In this chapter, participants will learn how to conduct a hazard analysis, to determine hazards that require a preventive control, and what resources are available to make this determination. These determinations are made by the Preventive Controls Qualified Individual (PCQI) in coordination with the facility's food safety team (as appropriate), and depend upon factors such as the specific animal food ingredients being used, the facility's operation and design, and the intended use of the animal food. The PCQI, in conjunction with the facility's food safety team, will utilize experience, training, and other resources to make these determinations. The requirements for conducting a hazard analysis are found in 21 CFR 507.33, which is found on page 56345 of the *Preventive Controls for Animal Food* rule.

21 CFR 507.33 – Hazard Analysis

- (c)(1) *The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section [biological, chemical, including radiological, and physical hazards] to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.*
- (2) *The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to the packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.*



Slide 3

In Chapter 3: Animal Food Safety Hazards, the requirement for hazard identification in 21 CFR 507.33(a) and (b) is discussed. This chapter will focus more on hazard evaluation, and the regulatory requirements for this process are outlined in this slide. Hazard evaluation must include an analysis of both severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

Environmental pathogens must be considered if animal food is exposed to the environment prior to packaging and does not receive a control measure that significantly minimizes the pathogen.

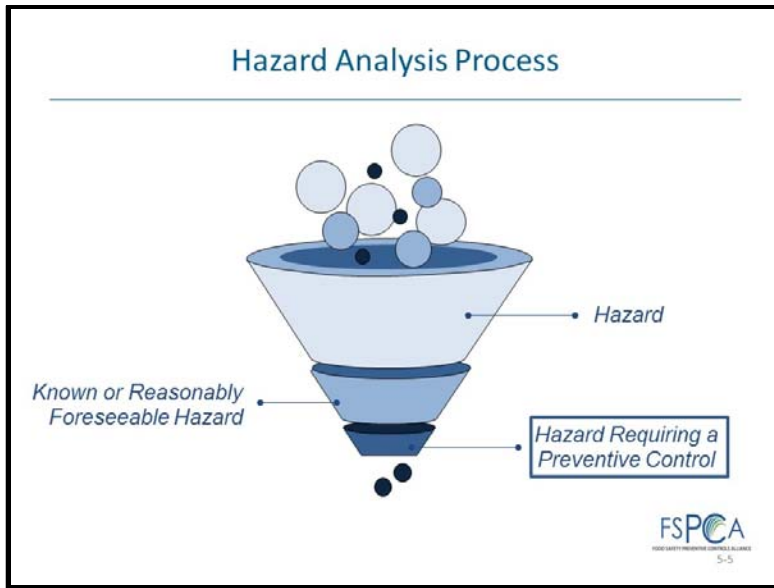
21 CFR 507.33 – Hazard Analysis

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



Slide 4

There are a number of factors that must be considered when evaluating the safety of finished animal food. Those are listed in this slide and will be discussed more in depth during this chapter.



Slide 5

In Chapter 3, the curriculum first introduced the difference between the defined terms *hazard*, *known or reasonably foreseeable hazard*, and *hazard requiring a preventive control*. This chapter will fully describe the necessary steps to conduct the analysis of a *known or reasonably foreseeable hazard* to determine if it falls into the narrowest category of those defined terms, which is a *hazard requiring a prevent control*.

Hazards Likely Vary Among Facilities

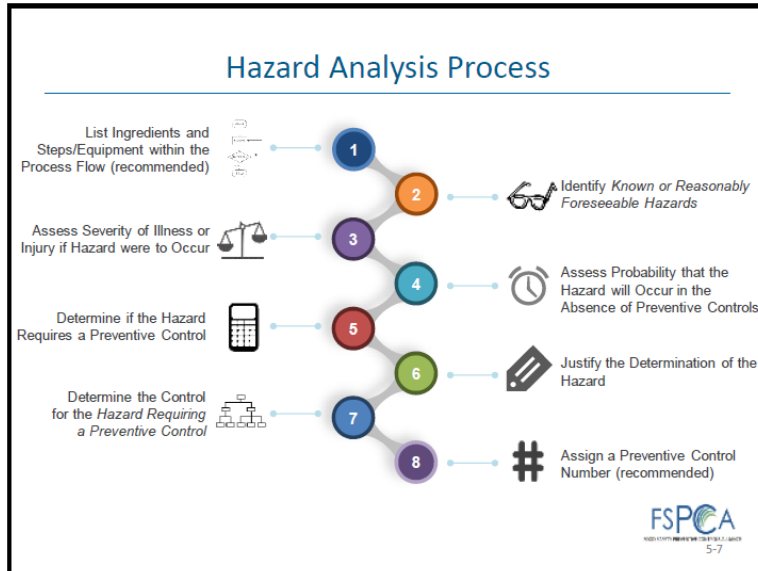
- Hazard identification and evaluation will likely vary among facilities.
 - Differences in known or reasonably foreseeable
 - Types of animal food manufactured, processed, packed, or held
 - Differences in those requiring preventive controls
 - Different severity
 - Different probability
 - Different prerequisite programs and CGMP activities



Slide 6

It is important to remember that the hazard evaluation process is likely to change from one facility to another. Because the types of animal food manufactured, processed, packed, or held will vary from one facility to another, the types of hazards that are known or reasonably foreseeable are likely to change. Furthermore, facilities that have similar *known or reasonably foreseeable hazards* may have other variables that impact the hazard evaluation. For example, the types of ingredients used, reasonable or intended use of the animal food, facility and process design, equipment, and environment may impact the severity and/or probability for the hazard.

Just as the identification and evaluation of a hazard can vary from one facility to another, a hazard's control can also be handled differently. Where one facility chooses to employ a combination of Supply-Chain-Applied Controls, Process Controls, and/or Sanitation Controls to address a single hazard, another may choose to utilize only one of those. Other facilities may use prerequisite programs, such as CGMPs, to reduce the probability of hazard occurrence to a sufficient level where the hazard does not require a preventive control. Remember that the ultimate goal is that safe animal food is produced. As long as that goal is being met, the variation in control methods among facilities is acceptable and expected given the flexibility of the *Preventive Controls for Animal Food* rule.



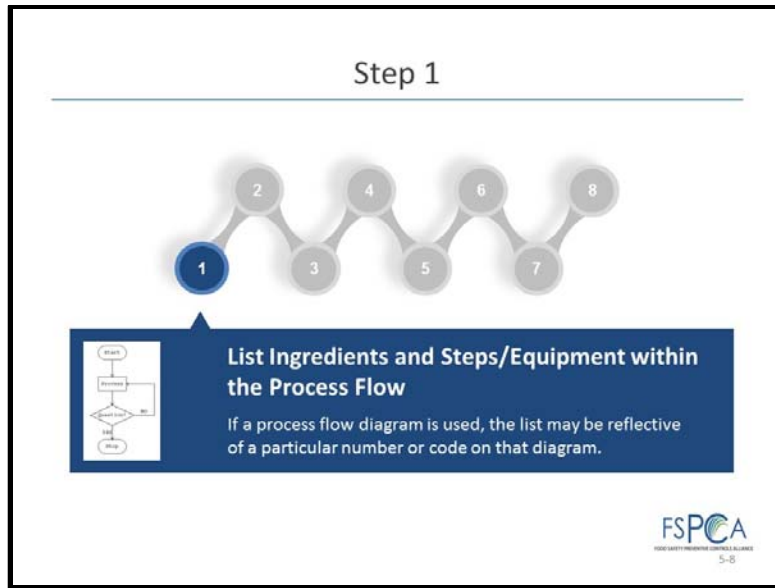
Steps 1 and 8 of this process are good industry practice recommendations but are not required to be part of the hazard analysis according to the *Preventive Controls for Animal Food* rule.

Slide 7

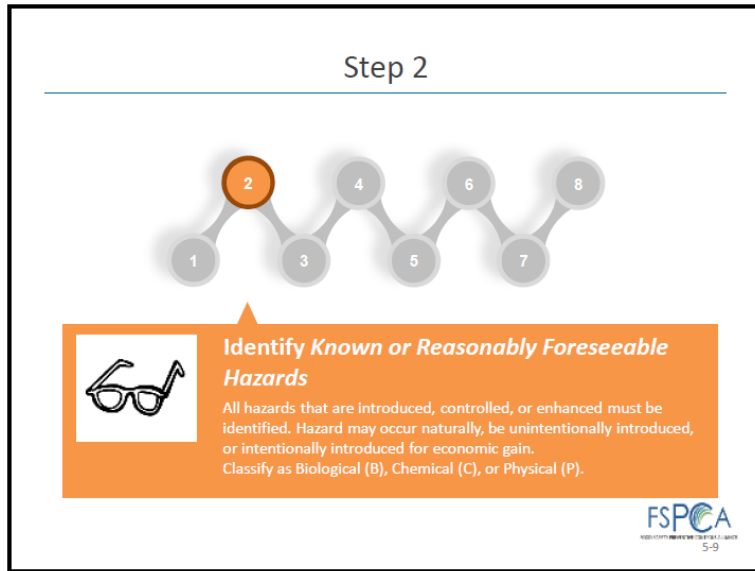
This slide shows a summary graphic of the hazard analysis process.

- Step 1: Use a flow diagram to identify steps and/or processing equipment (recommended)
- Step 2: Identify known or reasonably foreseeable hazards associated with the type of animal food a given facility manufactures, processes, packs, and/or holds
- Step 3: Assess known or reasonably foreseeable hazards for severity of illness or injury if the hazard were to occur
- Step 4: Assess known or reasonably foreseeable hazards for probability that the hazard will occur in the absence of preventive controls
- Step 5: Determine if the hazard requires a preventive control based on Steps 3 and 4
- Step 6: Justify the determination made in Step 5.
- Step 7: Determine the appropriate control for the hazard requiring a preventive control
- Step 8: Assign a preventive control number for traceability and identification purposes (recommended).

This slide is a snapshot of the required steps for hazard analysis and preventive controls determination. The rest of this chapter will focus on hazard identification and evaluation steps. The control measures and their management components will be discussed in detail in later chapters.

**Slide 8**

A flow diagram is a useful starting point for hazard identification. There are a variety of ways to use the flow diagram, such as by listing equipment directly or by listing the equipment by number or code. Ingredients and equipment can be considered individually or as logical groupings. For example, various grain by-products, such as corn distillers' grains with solubles and corn gluten meal, may be utilized by the facility and have similar hazards. Thus, they may be listed individually or grouped by collective terms when appropriate. Example grouping categories may be: grains, grain by-products, fats, receiving, conveying, storage, batching/mixing, pelleting/cooling, and load-out.

**Slide 9**

For each ingredient or processing step category, the facility must identify *known or reasonably foreseeable hazards*. This may be accomplished by listing biological, chemical, or physical hazards associated with each ingredient or processing step identified in Step 1. These hazards may occur naturally (such as aflatoxin), be unintentionally introduced (such as metal fragments), or intentionally introduced for economic gain (such as melamine). There is a specific definition for a *known or reasonably foreseeable hazard*, and it centers on the known or potential association of a hazard with the facility or the type of animal food being manufactured, processed, packed, or held.

Some facilities may choose to start with a broad list of hazards through a brainstorming session and narrow it to those that are known or reasonably foreseeable for their facility and animal food. Thus, some facilities may have a hazard that is *known or reasonably foreseeable*, while another may not consider the hazard to meet this threshold. For example, a pet food manufacturing facility may consider *Listeria monocytogenes* to be known or reasonably foreseeable, while a facility manufacturing food for poultry may not even though they use some common ingredients.

Items that Must Be Considered in Hazard Evaluation

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



While these items must be considered during hazard analysis, there does not need to be documentation that each was considered during the assessment. A facility may find it helpful to include notes about these considerations to explain the justification for decision making.

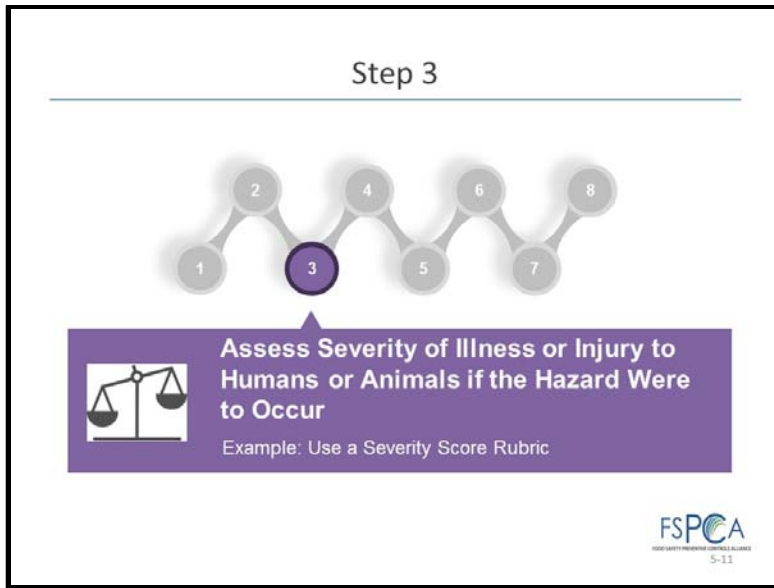
Further information regarding other relevant factors can be found in the Preamble of the *Preventive Controls for Animal Food* rule, particularly in comment and response 269.

The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) report on “Hazard Analysis and Critical Control Point Principles and Application Guidelines” contains a useful set of questions to consider when conducting hazard identification. This resource is available at:
<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#app-c>

Slide 10

There are a several items that must be considered when evaluating a *known or reasonably foreseeable hazard*. The facility must consider the items above when determining the safety of the animal food.

These considerations are largely a collection of the root cause(s) of hazards that have previously caused illness or injury in humans or animals. For example, improper formulation to reach a specific pH, raw materials and ingredients, and manufacturing/processing procedures may be linked to animal food not meeting the nutritional requirements of an intended species leading to a nutrient deficiency or toxicity hazard. Poor functionality of the equipment or design of a facility may result in physical contamination of the animal food, such as metal in the animal food, or improper mixing causing nutrient deficiencies or toxicities. Improper sanitation or housekeeping, storage, or transportation may lead to cross-contamination of animal food that may lead to a hazard. Finally, specific weather conditions during the growing season of crops may result in a greater likelihood of chemical hazards, such as mycotoxins.



Rubrics are a type of scoring guide or ranking system used to evaluate certain criteria, such as severity and probability. They help maintain consistency during assessment. For this reason, they may be useful when evaluating the severity or probability of a hazard in different types of ingredients or process steps.

Slide 11

Once hazards have been identified as known or reasonably foreseeable, the hazard evaluation process begins. This is where the facility must assess both the severity and probability of a hazard to humans and animals to determine if the hazard requires a preventive control. How this determination occurs may vary.

One example method to assess the severity of an illness or injury if the hazard were to occur is through the design and use of a severity assessment process where different levels of severity are designated with an alphanumeric key, also referred to as a rubric. This key may consider a number of items, such as the likelihood of mortality or morbidity, whether the hazard affects only animals or also humans, and the number of animals or humans potentially affected if a hazard were to occur.

Example Severity Score Rubric

- I: High = Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.
- II: Medium = Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.
- III: Low = Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.
- IV: Very Low = Illness or injury is minor. Possible to impact animals, unlikely to impact humans.

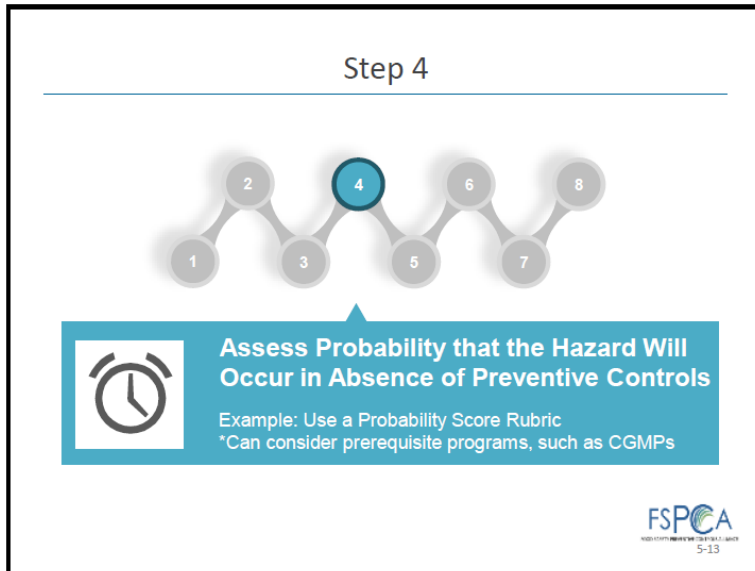


A rubric is one type of severity score method. Others may choose to use a metric based on recall classifications or other existing metrics used within the facility or business. A rubric is not necessary, but the severity and probability must be considered, and a rubric like this helps document that process.

Slide 12

In the example shown here, roman numerals are used to designate severity level.

- I = high severity, meaning they would cause imminent and immediate danger of death or severe sickness. This hazard is likely to impact both animals and humans.
- II = medium severity; danger and sickness may be severe, but it is not imminent or immediate. The hazard is likely to impact animal health, but only potentially affects human health.
- III = low severity; illness or injury may occur, but the impact is reversible. The hazard is likely to impact animal health, but is unlikely to affect human health.
- IV = very low severity; sickness or injury is minor. The hazard has potential to impact animal health, but is unlikely to impact human health.



Slide 13

In addition to severity, the probability that the hazard will occur in the absence of preventive controls must also be assessed. Remember that this assessment may take into account prerequisite programs, such as CGMPs, that may help reduce the probability of hazard occurrence. When assessing probability, the facility may choose to employ a scheme using a probability score assignment that is similar to that described for the severity score.

A facility should consider whether an effective prerequisite program (such as CGMP) reduces the probability that a *known or reasonably foreseeable hazard* may occur. This consideration may result in the facility determining that, based on the overall hazard analysis:

- the hazard does not require a preventive control;
- the hazard requires a preventive control and the prerequisite program is the preventive control; or
- the hazard requires a preventive control beyond the prerequisite program.

This prerequisite program must be effectively implemented to reduce the probability, thus having procedures and routine recordkeeping in place are a good industry practice.

Example Probability Score Rubric

- A: High = Immediate danger that the hazard will occur.
- B: Medium = Probably will occur in time if not corrected.
- C: Low = Possible to occur in time if not corrected.
- D: Very Low = Unlikely to occur; may assume hazard will not occur.



Slide 14

In the example used here, letters are used to represent probability of occurrence.

- A represents a high probability of occurrence; immediate danger that the hazard will occur if no mitigation measure is applied.
- B designates a medium probability of occurrence; the hazard probably will occur in time if no mitigation measures are applied.
- C designates a low probability of occurrence; it is possible for the hazard to be present in the animal food if no mitigation measures are applied.
- D designates a very low probability of occurrence; it would be unlikely for the hazard to be present in the animal food, or it could be assumed the hazard will not be present in the animal food.

Resources to Help Establish Probability and Severity

- FSPCA website
- Food and Drug Administration (FDA)
 - Recalls & Withdrawals
 - Reportable Foods Registry (RFR) for animal food/feed
 - Guidance for Industry
- Centers for Disease Control and Prevention (CDC)
- European Food Safety Authority
- World Animal Health Information Database



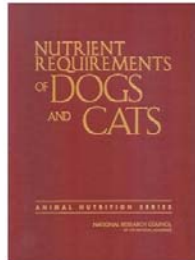
The FSPCA website is a good place to find resources and may contain links to the other resources listed on the slide. Many of the other resources listed may be found for free online, but others require annual dues or fees.

Slide 15

As can be imagined, the assessment of severity and probability is extremely important. When conducting this assessment, the facility will likely need to rely on its own experience and the historical occurrence of hazards within the facility. However, other resources should be used to help make this assessment, especially for the written justification. Many of these resources have been gathered on the website for the Food Safety Preventive Controls Alliance (FSPCA) for reference. There is information available from the FDA, including recalls and withdrawals associated with animal food and Reportable Food Registry (RFR) data for animal food/feed. The FDA will also be publishing several “Guidance for Industry” documents associated with this rule and links to those will be on FDA’s FSMA website upon their availability. Outbreak data associated with animal food can be found from the CDC. The European Food Safety Authority has a database of technical reports and guidance that may be helpful for a number of potential hazards. The World Animal Health Information Database is a comprehensive database of animal health and feed-associated disease event reports and health statuses on an international basis.

Resources to Help Establish Probability and Severity

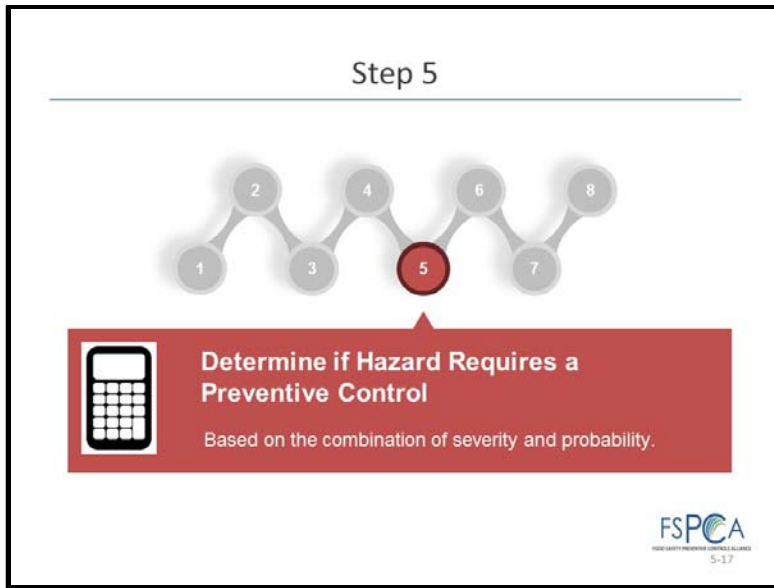
- National Research Council Nutrient Requirements
- Association of American Feed Control Officials (AAFCO) Official Publication
- Feed Additive Compendium
- Peer-reviewed research publications
- Trade association whitepapers



FSPCA
FEDERAL SPOILS PROGRAM
5-16

Slide 16

The National Research Council has publications updated on a regular basis regarding the nutrient requirements for various species, such as dogs and cats, beef cattle, dairy cattle, and swine. The Association of American Feed Control Officials, or AAFCO, Official Publication lists ingredient definitions, appropriate analytical methods, and has nutrient profiles for dog and cat food. The Feed Additive Compendium is an updated listing of regulatory and labeling requirements for feed additives, with a particular emphasis on animal drugs. Finally, peer-reviewed research publications and trade association white papers should be reviewed to understand the developing knowledge for different hazards, their severity, and their probability. Again, this is just a short list of some of the resources available that may be used when making an assessment of severity and probability. Many of these and other resources can be found on the FSPCA website.

**Slide 17**

The next step is to utilize the combination of severity and probability to determine if the hazard requires a preventive control. There are many different ways to make this assessment. We will show different ways to use the previous severity and probability rubrics in a matrix, but a specific score, rubric, or matrix is not required – just that the combination of severity and probability be considered when making the determination of a *hazard that requires preventive controls*.

Process to Identify Hazards and Controls

Hazard Evaluation Example

SEVERITY \ PROBABILITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

This type of matrix approach is not necessary, as long as severity and probability are both considered to determine if a hazard requires a preventive control.

Slide 18

In this matrix, the severity assessment described on slide 5-12 is listed along the top, while the probability assessment described on slide 5-14 is listed along the left side. The combination of severity and probability make a grid. The combinations in the upper left corner of the matrix, or those with high severity and probability, are more likely to require a preventive control than those that are in the lower right corner of the matrix, or those with a very low severity and probability.

Moving towards the lower right corner, the facility is less likely to determine a need for a preventive control for the hazard. Even though the assessment may identify a hazard with a lower severity and/or probability, the facility may still determine that such a hazard is one for which they want to establish a preventive control based on a business decision.

Process to Identify Hazards and Controls					
Hazard Evaluation Example					
		Critical	Moderate	Negligible	
PROBABILITY \ SEVERITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Slide 19

This is the same example as the previous slide but with a different way to use the same 2-way matrix. Some food safety teams may predetermine categories that represent health risks that are critical, moderate, or negligible. Potentially, their predetermined justification was that if hazards fall into the 'critical' category, which are marked in the darkest shade of gray, they would probably require a preventive control. Those hazards that fall into the 'moderate' category, marked by the medium shade of gray, may require a preventive control, or perhaps do not need a preventive control, but may require prerequisite programs, such as CGMPs, to reduce their probability. Finally, those hazards that fall into the 'negligible' category, marked by the lightest shade of gray, probably do not require a preventive control.

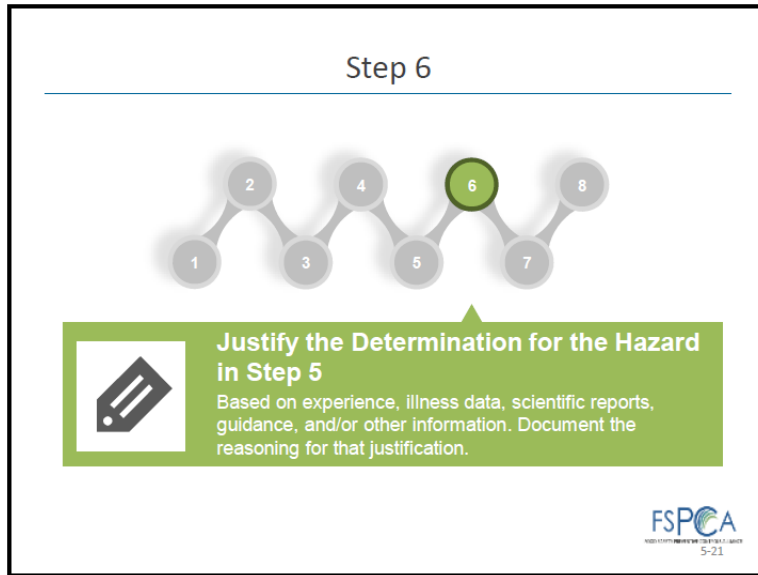
Even when utilizing the same 2-way matrix, one facility's determination to require a preventive control may be very different from another's. For example, the facility using this 2-way matrix may potentially be more accepting of risk, as not many of the classification boxes fall into the 'critical' category.

Process to Identify Hazards and Controls					
Hazard Evaluation Example					
		Critical	Moderate	Negligible	
PROBABILITY \ SEVERITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Slide 20

Alternatively, here is an example where the facility is more risk-averse. Again, this is the same 2-way matrix as the two previous slides but this time, a different facility has previously determined which part of the grids represent critical, moderate, or negligible animal food safety risks. This facility has identified more categories that are critical and fewer categories that are negligible compared to the facility that was more risk accepting on slide 5-19.

While these are examples to demonstrate a concept, it is important to recognize that the method of hazard evaluation is flexible. Facilities do not need to utilize a rubric scoring or create this type of 2-way matrix. Some may use a numerical scoring method, while others will not score severity and probability at all, and will instead just consider them in the evaluation process. The important point is that there are many methods to reach the final determination, but both severity and probability must be considered when evaluating if a *known or reasonably foreseeable hazard* reaches the threshold of a *hazard requiring a preventive control*.



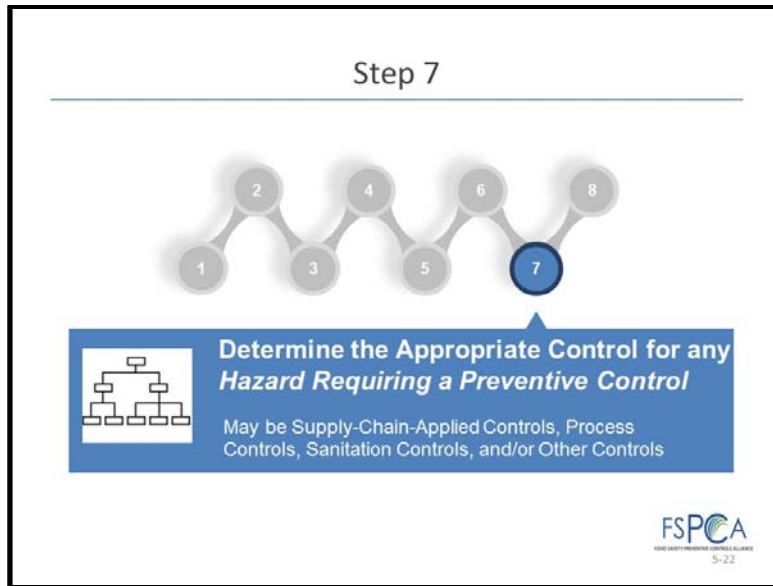
Slide 21

Once it has been determined if a hazard requires a preventive control in Step 5, the determination should have written justification. This justification is to be based upon facility experience, illness data, scientific reports, guidance, or other information, such as that discussed in the resources slides of this chapter. This justification must be documented. Notably, hazards that are determined to not need a preventive control must also have written justification. The facility should be prepared to explain their justification for this determination.

Clear justification is necessary, particularly if hazard analysis determines a *known or reasonably foreseeable hazard* is not a hazard requiring a preventive control.

Justification should be defensible by facility personnel to employees, customers, and regulatory officials, even though the determination is made by the *Preventive Controls Qualified Individual* and is the responsibility of the owner, operator, or agent in charge of the facility. In order for facility personnel to properly communicate the justification in the absence of the PCQI, it may be necessary to describe the justification fully in bulleted or paragraph form. This may be accomplished within the hazard analysis section or as an appendix.

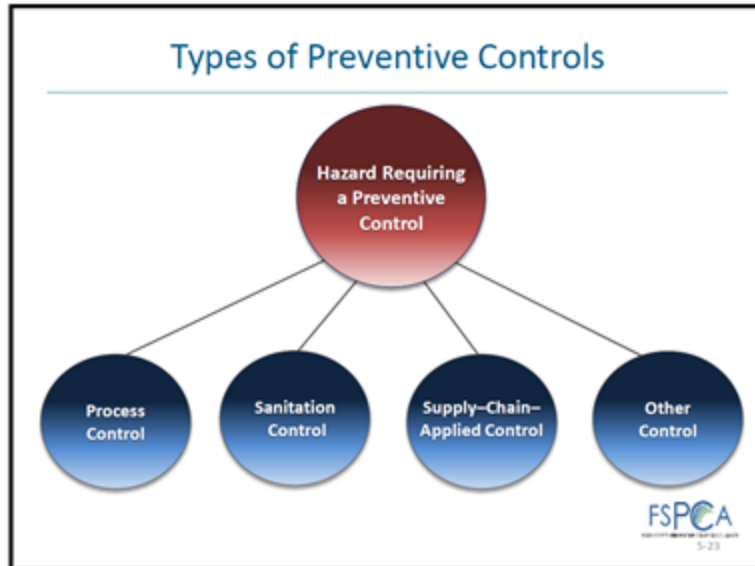
Comment and response 247 in the Preamble of the *Preventive Controls for Animal Food* rule has additional explanation.



For those familiar with HACCP food safety systems, keep in mind that not all preventive controls are critical control points. Thus, the actions that are taken for other preventive controls may be different than those required for critical control points.

Slide 22

If the evaluation determines that the hazard requires a preventive control, the type(s) of preventive controls must then be determined. Preventive controls may include Process Controls, Sanitation Controls, Supply-Chain-Applied Controls, and/or Other Controls. Some hazards may be controlled by a single preventive control, while others may have multiple controls. The various types of preventive controls will be discussed in other chapters.

**Slide 23**

The appropriate control for a hazard is based on the type of hazard, the type of animal food, and the type of facility.

Process controls are used to ensure the control of parameters during manufacturing or processing. Most of the preventive controls in the animal food industry will be process controls, such as extrusion, or flushing or sequencing procedures, which are described in Chapter 7.

Sanitation controls are used to ensure the facility is maintained in a sanitary condition adequate to minimize or prevent hazards, such as environmental pathogens and biological hazards due to employee handling. Most of the sanitation controls in the animal food industry will focus on biological hazards. Examples of sanitation controls would be sanitizing animal food contact surfaces or hygienic zoning, which are described in Chapter 8.

Supplier controls, or supply-chain-applied controls, are used when a hazard in raw material or ingredient is controlled before its receipt. There may be limited applicability of this type of control to parts of the animal food industry. Supply-chain-applied controls will be described in Chapter 9.

There is another category of preventive controls, called Other Controls, when the control does not fit the definition of these other controls. There is limited discussion of these occurrences in this curriculum, but examples may be hygiene training or if a *hazard requiring a preventive control* is controlled through a current CGMP or other prerequisite program.

21 CFR 507.36 – Circumstances in which a Facility is not required to Implement a Preventive Control

- Special circumstances exist where an ingredient/raw material supplier does not need to establish a preventive control for a hazard requiring a preventive control:
 - You determine and document the type of animal food could not be consumed without application of an appropriate control; or
 - You rely on your customer to ensure the identified hazard will be significantly minimized or prevented (by themselves or an entity further downstream in the distribution chain).



Slide 24

21 CFR 507.36 provides circumstances that allow a manufacturer/processor to not implement a preventive control for a hazard requiring a preventive control. These circumstances include when a facility determines and documents that the type of animal food could not be consumed without application of an appropriate control or if the facility relies on a downstream entity or customer to apply the preventive control.

An example application of an industry segment relying on a customer to apply the preventive control may be a facility manufacturing animal by-product meal. The facility determines that *Salmonella* spp. in the meal is a *hazard requiring a preventive control*, but instead of controlling the hazard in the meal, the facility requires assurance from its customer (an extruded pet food company) that preventive controls will be implemented at the downstream facility to control *Salmonella* spp. In this case, the supplier of the meal may manufacture and ship the animal food to the pet food manufacturer because it has an intended downstream process control.

21 CFR 507.36 – Circumstances in which a Facility is not required to Implement a Preventive Control

- If a facility relies on a downstream entity to significantly minimize or prevent a hazard, the supplying facility must:
 - Disclose in documents accompanying the animal food that it is “not processed to control [identified hazard]”; and
 - Annually obtain written assurance from your customer that complies with Subpart F requirements that:
 - The customer has established and follows specified procedures that will significantly minimize or prevent the hazard; or
 - The customer has determined that the identified hazard is not a hazard requiring a preventive control for the intended species, including the species and justification for the determination.



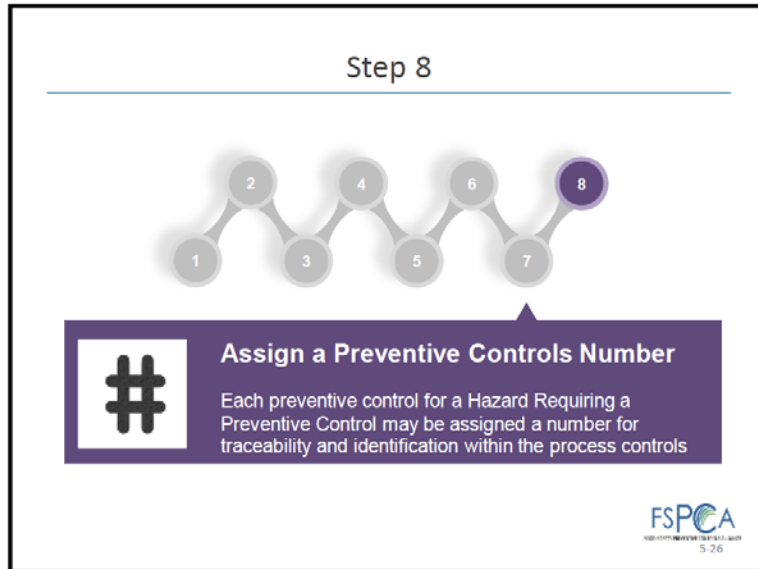
The recordkeeping requirements of Subpart F relating to these written assurances can be found on Slide 1-47.

Slide 25

If a facility uses 21 CFR 507.36 to pass control of a hazard to its customer (or another downstream manufacturer), the facility must complete two key requirements, but the timeframe for the completion of these requirements is different.

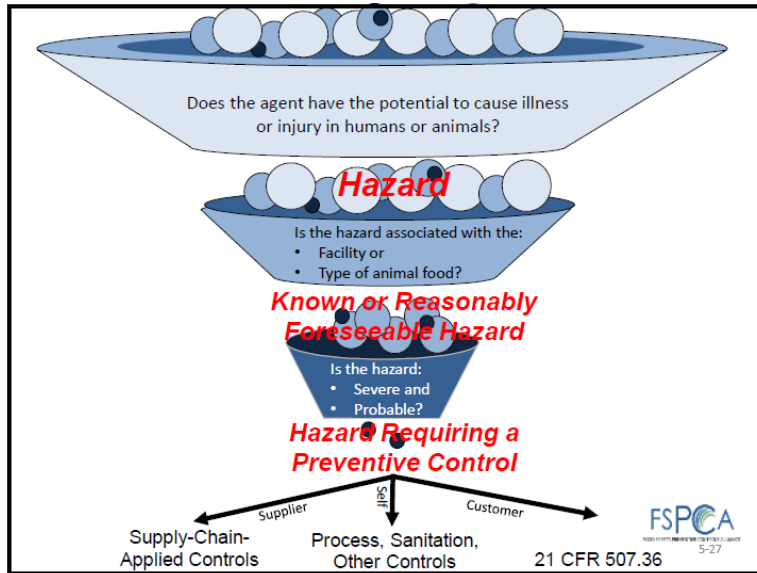
- First, the facility must disclose in documents accompanying the animal food that the animal food is “not processed to control [identified hazard].” This requirement begins whenever the facility must begin complying with Subpart C.
- Second, the facility must annually obtain written assurance that the customer has established and is following procedures (identified in the written assurance) that they will significantly minimize or prevent the identified hazard. Since the publication of the final rule in September 2015, the FDA has published a subsequent extension that extends the compliance requirement for facilities obtaining these written assurances from the original compliance date for subpart C for each business size category. With this extension, the first time facilities that are not small or very small businesses must begin to annually obtain these written assurances is September 18, 2019.

These written assurances must follow the specified recordkeeping requirements in Subpart F.



Slide 26

A best practice recommendation is to assign a preventive control number to all *hazards requiring a preventive control*. Having a number designation for each preventive control in the Food Safety Plan can be helpful to identify and track the preventive control. This concept and other options for documenting the hazard identification and evaluation steps is demonstrated in the next few slides.



The *Preventive Controls for Animal Food* rule does not require facilities to list all hazards during hazard identification and evaluation, only those that *Known or Reasonably Foreseeable*. Some facilities may choose to start with a broader list of hazards, which is acceptable, but not required.

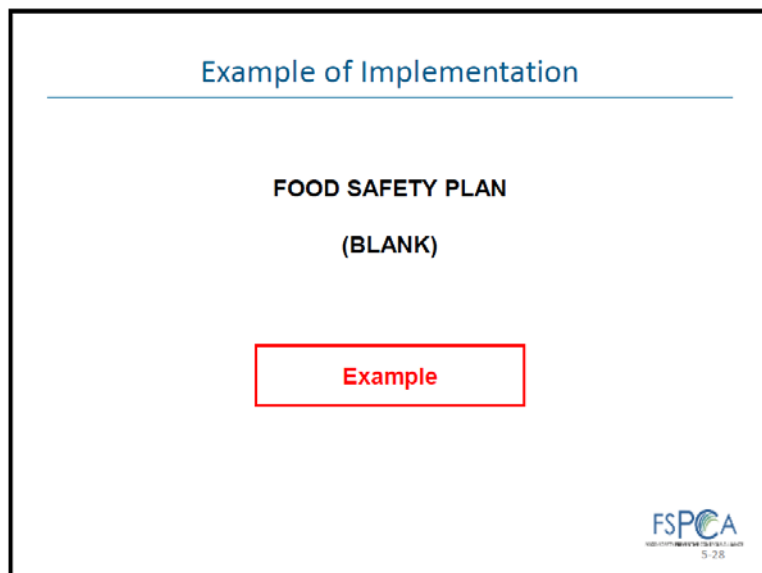
Slide 27

This is a summary of the hazard identification and evaluation process. If an agent has the potential to cause illness or injury in humans or animals, then it is by definition, a *Hazard*. The broad category of a *hazard* is then narrowed to only those agents that are associated with the facility or type of animal food, which are then considered to be a *Known or Reasonably Foreseeable Hazard*.

Next, a *Known or Reasonably Foreseeable Hazard* is evaluated for its severity and probability by considering the 10 items previously described on Slide 5-10, such as transportation practices, intended or reasonably foreseeable use, or condition, function, and design of the facility and equipment.

If the combination of severity and probability is high, even when considering prerequisite programs, such as CGMPs, the agent is then a *Hazard Requiring a Preventive Control*.

At that point, the type of control can vary. For example, the facility can ask a supplier to control the *Hazard Requiring a Preventive Control* by using a Supply-Chain-Applied Control, which will be described in the Supply Chain Program in Chapter 9. The facility could control the *Hazard Requiring a Preventive Control* itself using a Process Control, Sanitation Control, or Other Control. There are also circumstances when a facility may ask its customer or downstream user of the animal food to control the *Hazard Requiring a Preventive Control*, at which the written assurances and disclosure statements described in Slides 5-24 and 5-25 would be utilized.



This section describes one part of the Example Food Safety Plan. The full plan and all associated records must meet the record requirements that were described in Chapter 1. For example, records must include information to identify the facility, the date (and time when appropriate), the signature or initial of the person performing the activity, and the identity of the product and lot code, if any. The Food Safety Plan must also be signed and dated by the owner, operator, or agent in charge of the facility upon completion and any modification.

Slide 28

This next section is just one example of how a facility may choose to organize and document the hazard identification and evaluation process in the Food Safety Plan. As with all examples in this curriculum, the example is just one way to accomplish the required activities. First, a blank plan is shown to discuss the key components. To help emphasize when one step transitions to another, the identification steps have been outlined in blue (columns 1 and 2), the evaluation steps in red (columns 3 through 6), and the control steps in green (columns 7 and 8).

If this was printed in black and white or grey scale, the colors will not be visible in this manual but the column numbers can be referenced as listed above.

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

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

Hazard Analysis Form Example -
other formats may be used

FSPCA
5-29

Slide 29


The format of this slide is important to review because similar formats will be used for the rest of the chapter. The top has a table where product information, the facility name, and the facility address can be included. In addition, there is a place for a page number, an issue date, and a date documenting if one version supersedes another to track historical changes to the Food Safety Plan.

The middle of the slide shows a table that is formatted similarly to Table 1 in the example Food Safety Plans. The first section in blue (columns 1 and 2) is hazard identification, where the ingredients or processing steps from the flow diagram can be recorded (Step 1). Next, the *known or reasonably foreseeable hazards* can be listed within each ingredient or processing step and grouped by classification as biological denoted with a (B), chemical denoted with a (C), or physical denoted with a (P) (Step 2). Some facilities may choose to have an additional column here or elsewhere in their hazard analysis listing a number of hazards that may not be known or reasonably foreseeable as they go through the hazard identification process. That is acceptable, as is more specific or broader grouping of ingredient and process step categories.

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Evaluation			
(3)	(4)	(5)	(6)
Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5

Hazard Analysis Form Example -
other formats may be used


FEDERAL SUPPLY PROGRAM
5-30


Slide 30

Next, columns 3 through 6 (in red) show the hazard evaluation steps. The hazard evaluation only needs to take place for those hazards that are known or reasonably foreseeable. The hazard analysis must include an assessment of severity of illness or injury to humans and animals if the hazard were to occur and the probability the hazard will occur in the absence of a preventive control. In this example, the severity and probability of the hazard are recorded in columns 3 and 4, respectively. Column 5 is used to record the determination of whether the hazard requires a preventive control and this can simply be done using a Yes or No designation. Lastly, column 6 is where the justification for that decision would be recorded. The justification may be longer than what can reasonably fit into a table. In those cases, the facility may choose to use appendices for lengthy explanations or maintain reference documents (such as scientific or technical articles) as part of its justification.

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Preventive Control(s)	
(7)	(8)
Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number

Hazard Analysis Form Example -
other formats may be used


FSPCA
FOOD SAFETY PROMOTION COUNCIL OF AMERICA
5-31

Slide 31

Finally, the preventive control that will be used to significantly minimize or prevent the hazard is shown in green (column 7). Column 8 is used to designate a preventive controls number that will be used to more clearly denote specific control measures and their management components, which are shown in Table 2 of the example Food Safety Plans and will be discussed in chapter 6. For now, that is the end of Table 1 and the example documentation for hazard identification and evaluation. The next section progresses through this table for both of the example Food Safety Plans.



Slide 32

The first implementation example for a hazard analysis and preventive control determination discussed is for the multi-species medicated and non-medicated feed manufacturing facility. To proceed with the example, start with the flow diagram that has been provided for this facility. Not every process step or ingredient will be listed in this example. To remain concise, the example has been limited to a single category of ingredients and shown a combination of process steps together. In a full Food Safety Plan, a more comprehensive consideration of process steps and/or ingredients may be necessary to conduct a thorough hazard analysis.

Livestock Feed Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy
Table 1. Hazard Analysis			
Identification			
(1)	(2)		
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards		
Ingredients	B1	Salmonella spp.	
	B2	BSE	
	C1	Copper toxicity	
	C2	Mycotoxins	
	P	Stones, metal	
Hand addition of ingredients	B	None	
	C	Copper toxicity	
	P	Foreign material: glass, metal, paper, plastic	
Mixing	B	None	
	C	Copper toxicity	

Slide 33

This hazard analysis is for the multi-species medicated and non-medicated animal food from “ABC Feed Mill in Anywhere, USA.” This is an abridged example; all ingredients were grouped together for hazard analysis and only two of the process steps are shown. The *known or reasonably foreseeable hazards* for each ingredient or process step category are listed by their classification as biological (B), chemical (C), or physical (P) hazards. In the ingredients category, *Salmonella* spp. and bovine spongiform encephalopathy (BSE) are biological hazards, and are identified because *Salmonella* spp. has been associated with some of the ingredients used by the feed mill and the facility feeds cattle. The facility manufactures food for sheep and also uses several ingredients that have high added copper levels, such as copper sulfate and beef and swine trace mineral premixes. Thus, copper toxicity in sheep resulting from an incorrectly labeled inbound ingredient may be a chemical hazard, particularly with sheep trace mineral premix. Another category of chemical hazards are mycotoxins that may be associated with different grains used by the facility. Stones and metal are also *known or reasonably foreseeable hazards* in the ingredients in this facility, and would be characterized as physical hazards.

There are also hazards listed for the hand addition of ingredients and mixing. Not all ingredients or process steps have biological, chemical, or physical hazards, such as there being no *known or reasonably foreseeable hazards* in the biological category for mixing. Meanwhile, some steps may have multiple hazards in a single category, such as the hand addition of ingredients potentially having glass, metal, paper, or plastic physical hazards.

Livestock Feed Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y	
PLANT NAME	ABC Feed Mill		ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	II - Medium	D – Very Low	No	FDA CPG 690.800; Li et al., 2012; see Statement 1
Copper toxicity in sheep	I – High	B - Medium	Yes	Multispecies premixes used by facility, copper toxic to sheep
Stones, metal	IV – Very Low	B - Medium	No	Grates employed over receiving pit, feed cleaner, magnets checked weekly for ferrous metal

Slide 34

This slide is a continuation of the hazard analysis from slide 3-30. This slide focuses on only three of the hazards listed in the ingredients category: *Salmonella* spp., copper toxicity in sheep, and stones or metal. Because these are *known or reasonably foreseeable hazards*, the facility must assess severity of illness or injury to humans or animals if the hazard were to occur and the probability of occurrence in the absence of preventive controls in order to determine if the hazard is a *hazard requiring a preventive control*.

Salmonella spp.: In this example, the facility determined the severity of illness or injury from *Salmonella* spp. in the animals for which the food is intended was II - Medium. Next, the probability of occurrence of the hazard was evaluated as D - Very Low. Due to this combination, the facility determined *Salmonella* spp. was not a *hazard requiring a preventive control*. The brief justification for this determination is listed as FDA CPG 690.800; Li et al., 2012, but there is a note to see *Statement 1*, where there is a more thorough explanation.

Copper toxicity: During the severity assessment for copper toxicity, it was determined that the hazard in sheep was I - High. The probability of occurrence for the hazard was determined to be B - Medium because there are ingredients containing high levels of added copper utilized within the facility, such as copper sulfate and trace mineral premixes for other species. The facility determined this combination of a high severity and medium probability warranted a preventive control.

Metal: Finally, the severity assessment for metal was determined to be IV - Very Low. Its probability was B - medium because metal has been associated with inbound ingredients, but there are components in place to reduce its probability, such as grates over the receiving pit, a feed cleaner, and magnets for ferrous metal that are checked weekly. While the probability was medium, the severity was low enough that the facility determined that a preventive control was not necessary. Note the justification for this hazard is relatively short and can be embodied within the single cell.

The information in Columns 3 and 4 is a reference to the severity and probability assessment in the rubrics described in Slides 5-12 and 5-14.

Not all facilities may evaluate these hazards to the same severity and probability. These examples are utilized as teaching concepts.

Resources cited in column 6 include the **FDA Salmonella Compliance Policy Guide 690.800, *Salmonella* in Food for Animals** and Li, X., et al. "Surveillance of *Salmonella* prevalence in animal feeds and characterization of the *Salmonella* isolates by serotyping and antimicrobial susceptibility." *Foodborne pathogens and disease* 9.8 (2012): 692-698.

Example A of Justification for *Statement 1*

- *Salmonella* spp. is not a hazard requiring a preventive control in this facility because:
 1. There are few types of *Salmonella* that are concerns for the types of animals my feed is intended.
 - a) Only *Salmonella* Pullorum, Gallinarum, Enteritidis, Choleraesuis, Abortusovis, Abortusequi, Newport, and Dublin, (FDA CPG 690.800).
 2. Those types that are a concern have been shown to not be prevalent with animal feed or ingredients (Li et al., 2012).

5-35

Slide 35

This shows some example justification language that the facility included to further explain why *Salmonella* spp. was a *known or reasonably foreseeable hazard*, but was not a *hazard requiring a preventive control*. Additional justification outside the Table form may be helpful so facility personnel can explain the decisions made during hazard analysis, particularly in the absence of the PCQI. The justification is as follows:

- *Salmonella* spp. is not a hazard requiring a preventive control in this facility because:
 1. There are few types of *Salmonella* that are concerns for the types of animal food manufactured within this facility. Only select serotypes (Pullorum, Gallinarum, Enteritidis, Choleraesuis, Abortusovis, Abortusequi, Newport, and Dublin) are known to be pathogenic in the animal species for which feed is manufactured at this facility. This is according to the *Salmonella Compliance Policy Guide 690.800*.
 2. Those serotypes that are a concern have been shown to not be prevalent with animal feed or ingredients. This is according to a scientific paper, Li et al., 2012.

Example B of Justification for *Statement 1*

- Although it is known or reasonably foreseeable that *Salmonella* spp. may be associated with the ingredients used in the facility and the type of animal food we manufacture, its moderate severity (II – Medium) and probability (D – Very Low) determine that it is not a hazard requiring a preventive control because:
 - Severity: If the hazard were to occur, *Salmonella* may cause illness to animals, but only if it were the serotype pathogenic to the type of animal food being manufactured. According to the FDA Salmonella Compliance Policy Guide 690.800, the serotypes of *Salmonella* we must be concerned with include poultry: Pullorum, Gallinarum, or Enteritidis; swine: Choleraesuis; sheep: Abortusovis; equine: Abortusequi; and cattle: Newport or Dublin. In addition, there is limited contact between this type of animal food and humans because this animal food is not typically used in the home. Thus, there is limited impact on human health.
 - Probability: Scientific research reported the frequency with which different *Salmonella* serotypes were found in animal food and ingredients. Of the serotypes relevant to our facility and identified in the severity section above, none were within the top 25 most prevalent serotypes reported. This report is: Li, X., et al. "Surveillance of *Salmonella* prevalence in animal feeds and characterization of the *Salmonella* isolates by serotyping and antimicrobial susceptibility." Foodborne pathogens and disease 9.8 (2012): 692-698.

5-36

Slide 36

Another facility may choose to use the same reasoning for making this determination, but may choose to format their justification in a more thorough manner. For example, the facility may choose to format it in paragraph form and show as follows:

Although it is known or reasonably foreseeable that *Salmonella* spp. may be associated with the ingredients used in the facility and the type of animal food manufactured, its moderate severity (II – Medium) and probability (D – Very Low) determine that it does not require a preventive control.

- Severity: If the hazard were to occur, *Salmonella* may cause illness to animals, but only if it were the serotype pathogenic to the type of animal food being manufactured. According to the FDA Salmonella Compliance Policy Guide 690.800, the serotypes of *Salmonella* of concern to cattle include: Newport or Dublin; goats: none; poultry: Pullorum, Gallinarum, or Enteritidis; sheep: Abortusovis; equine: Abortusequi; and swine: Choleraesuis. In addition, there is limited contact between this type of animal food and humans because this animal food is not typically used in the home. Thus, there is limited impact on human health.

The justification goes on to discuss probability:

- Probability: Scientific research reported the frequency with which different *Salmonella* serotypes were found in animal food and ingredients. Of the serotypes relevant to this facility and identified in the severity section above, none were within the top 25 most prevalent serotypes reported. This report is: Li, X., et al. "Surveillance of *Salmonella* prevalence in animal feeds and characterization of the *Salmonella* isolates by serotyping and antimicrobial susceptibility." Foodborne pathogens and disease 9.8 (2012): 692-698.

Due to the medium severity and very low probability for the hazard in the type of animal food the facility manufactures, the determination was made that *Salmonella* spp. was not a hazard requiring a preventive control.

Livestock Feed Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis		
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify Known or Reasonably Foreseeable Hazards	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
<i>Salmonella</i> spp.	n/a	n/a
Copper toxicity in sheep	Supply-Chain-Applied Control - Control of copper level in sheep mineral premix	1
	Process Control - Procedures for ensuring correct manual weighing and addition of sheep mineral premix	2
	Process Control - Procedures for mixing and sequencing of food for sheep	3
Stones, metal	n/a	n/a

FSPCA
5-37

In this example, 3 different preventive controls are utilized to prevent copper toxicity. These were selected as practical preventive controls because the facility already has similar procedures in place for controlling medicated feed additives as a licensed feed mill to follow the CGMPs for 21 CFR 225. Other facilities may choose to have single or multiple preventive controls to significantly minimize or prevent a *hazard requiring a preventive control*.

Slide 37

While the only *hazard requiring a preventive control* was copper toxicity, a total of 3 preventive controls were determined necessary to significantly minimize or prevent the hazard. First, the facility determined that the incoming copper level of sheep mineral premix must be known and controlled. Second, there must be standard procedures for ensuring correct manual weighing and addition of the sheep mineral premix, particularly to prevent incorrect addition or unintentional use of a mineral premix for a different species that may cause copper toxicity when manufacturing food for sheep. Third, there must be standard procedures for ensuring adequate mixing and mixer cleanout so carryover of other feeds does not cause copper toxicity in food for sheep. These preventive controls are numbered sequentially and their specific controls will be discussed more fully in later chapters.

Comparison of Hazard Evaluation		
• Example: Copper toxicity in premix addition step in food for sheep		
Hazard Evaluation	Facility 1	Facility 2
Is the hazard known or reasonably foreseeable?	Yes	Yes
Severity	I - High	I - High
Probability	C - Low	B - Medium
Does the hazard require a preventive control?	No	Yes
Justification	Single mineral premix used by facility, weighed by automation. Facility procedures used to ensure automation works properly.	Other mineral premixes with high copper levels. Premixes are weighed manually.
Preventive Control	None	Receiving of ingredients with added Cu; Hand-add of ingredients with added Cu; Mixing, sequencing of sheep feed
Preventive Control Management Requirements	None	Monitoring, Corrective Actions, Verification, Record Review, Recall Plan

Slide 38

This is a side-by-side example of two facilities that, due to differences in equipment and raw materials, are addressing the same hazard of copper toxicity in different ways. Facility 1 does not require a preventive control, while Facility 2 requires a preventive control at this step. Both of these facilities manufacture food for sheep, so in both cases, copper toxicity is listed and determined to be a *known or reasonably foreseeable hazard*. The severity is I - High for both facilities due to the severe implications of copper toxicity in sheep.

Facility 1 evaluated the hazard to have a C – Low probability, and therefore, the facility determined copper toxicity was not a hazard requiring a preventive control. Facility 1 made this determination because the facility does not have mineral premixes for other animal species that may contain a concerning level of copper, so the probability for copper toxicity by an employee unintentionally including the incorrect mineral premix is reduced. Furthermore, the premix is weighed out by an automation system from a microsystem and procedures ensure that the microingredient bins are accurate, precise, and calibrated, which further reduces the likelihood of hazard occurrence. Because the hazard does not require a preventive control in Facility 1, there are no required preventive control management components.

While Facility 2 had the same severity for the hazard, the facility evaluates that copper toxicity in sheep has a probability of occurrence of B - Medium and requires a preventive control. This is because Facility 2 utilizes mineral premixes for other animal species that have high added copper levels, and their accidental use in food for sheep may result in toxicity. In addition, the mineral premixes are all weighed manually, which enhances the chance for weighing error. Because of the difference in probability assessment, Facility 2 determined copper toxicity was a *hazard requiring a preventive control*.

Because Facility 2 implements preventive controls for copper toxicity, Facility 2 requires the necessary preventive controls management components, such as monitoring, corrective actions, verification, record review, and a recall plan. Management components will be discussed in chapter 6, but this example illustrates how two facilities can assess probability of the same hazard in different ways, and may come to different conclusions about the necessity for a preventive control.



Slide 39

The second implementation example for a hazard analysis and preventive control determination discussed is the example Food Safety Plan for dry extruded dog and cat food. Participants should reference the flow diagram for this example plan during the discussion.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis		
Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards	
Ingredients	B	<i>Salmonella</i> spp.
	C	Thiamine deficiency
	P	Foreign material: metal, plastic, bone, glass, wood
Bulk receiving	B	<i>Salmonella</i> spp.
	C	None
	P	Foreign material: metal, plastic, glass, wood
Mixing	B	None
	C	Thiamine deficiency
	P	Metal

Slide 40

This is an abridged example; all ingredients were grouped together for hazard analysis and only two of the process steps are shown. The *known or reasonably foreseeable hazards* for each ingredient or process step category are listed by their classification as biological (B), chemical (C), or physical (P) hazards.

In the example for dry extruded dog and cat food from ABC Pet Food, incoming ingredients are sources of known or reasonably foreseeable hazards. *Salmonella* spp. is listed as a known or reasonably foreseeable hazard because the ingredients used by the pet food facility have been known to be a source of the pathogen. In fact, the facility knowingly purchases ingredients that may be contaminated with *Salmonella* because it plans to control the hazard during processing. In addition, metal, plastic, bone, glass, or wood are all physical hazards that may be associated with incoming ingredients.

Bulk receiving typically contains an open entry point into the manufacturing system, where a variety of foreign material may enter if it crosses the receiving pit grating. Examples of foreign material that may be in the bulk receiving area include metal, plastic, glass, or wood.

Finally, mixing is a manufacturing/processing step in which the facility identified a known or reasonably foreseeable hazard. Improper mixing may prevent the thiamine premix from being fully incorporated in cat food and lead to thiamine deficiency. Mixers are also made of metal, and may introduce the hazard during the process.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	I - High	A - High	Yes	FDA Salmonella CPG 690.800
Thiamine deficiency (cat)	II - Medium	C - Low	No	COA used by known supplier with historical data to confirm values.
Metal	II - Medium	B - Medium	Yes	Ingredients may include non-ferrous metal that may not be caught by a magnet

According to the **FDA Salmonella Compliance Policy Guide 690.800, *Salmonella* in Food for Animals**, pet food poses a significant risk when humans come in contact with it because it may be “ingested directly by humans from their hands or utensils that are contaminated when they feed their pets. Certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems, are particularly susceptible to acquiring salmonellosis from pet food and may experience more severe symptoms. Additionally, animals may become infected, either asymptotically or clinically, with *Salmonella* from the pet food, thus increasing the potential human exposure.”

Slide 41

As with the livestock feed example, *known or reasonably foreseeable hazards* must be evaluated for severity and probability to determine if they are *hazards requiring a preventive control*. Justification is required, particularly for those hazards that do not require a preventive control. In this example, only the assessment of *Salmonella* spp., thiamine deficiency in cats, and metal are described in the ingredients section.

Salmonella spp.

The facility assessed *Salmonella* to have I - High severity as it is known to potentially cause both human and animal illness. The hazard was determined to have A - High probability because it is likely present in some of the ingredients. This combination warranted the determination that *Salmonella* was a *hazard requiring a preventive control*, with several factors impacting this justification. First, there is data to support that *Salmonella* in pet food has been linked to illness in humans. Second, there are numerous recalls of pet food for *Salmonella* contamination. Finally, FDA's Salmonella Compliance Policy Guide states there is zero tolerance for *Salmonella* in pet food.

Thiamine deficiency


The facility determined the severity of thiamine deficiency in cats was II - Medium because the hazard may lead to serious illness or death in cats, but would not impact human health. The probability of hazard occurrence was evaluated as C - Low because the facility requires certificates of analysis from its cat mineral premix supplier and has historical data demonstrating the supplier's compliance with declared values. This data will be provided upon official request.

Metal

Finally, the facility determined that the severity of metal is II-Medium because it could cause a more substantial impact based on the eating behavior and other factors, which will be described later. The probability was assessed as B - Medium because the ingredients may include non-ferrous metal that may not be caught by a magnet. The facility determined that this combination of severity and probability warranted a preventive control.

Pet Food Example		
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food	PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES mm/dd/yy

Table 1. Hazard Analysis		
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify Known or Reasonably Foreseeable Hazards	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
Salmonella spp.	Process Control - Extrusion temperature	1
	Sanitation Control - Post-extruder surface sanitizing	2
Thiamine deficiency (cat)	n/a	n/a
Metal	Process Control - Metal detection of finished pet foods	3



FEDERAL PET FOOD & SUPPLY ASSOCIATION

5-42

Slide 42

The facility determined that *Salmonella* should be controlled by two different preventive controls. The first preventive control is the application of a commercial heat step, which is a process control because there would be a minimum temperature required during extrusion. The commercial heat step, which is achieved through extrusion, is identified as preventive control number 1. The second preventive control would be the use of sanitation controls to prevent post-processing cross-contamination, and this preventive control has been assigned number 2.

Metal was determined to be controlled by metal detection of finished pet food, which would be a process control and preventive control number 3. Again, the control measures and their required management components will be described in coming chapters, but this describes the hazard analysis process for this example Food Safety Plan.

Comparison of Hazard Evaluation		
• Example: Metal in the example Food Safety Plans		
Hazard Evaluation	Multi-Species Food	Dog and Cat Food
Is the hazard known or reasonably foreseeable?	Yes	Yes
Severity	IV – Very Low	II - Medium
Probability	B - Medium	B - Medium
Does the hazard require a preventive control?	No	Yes
Justification	Low likelihood to cause illness or injury in animals. Very low likelihood in humans.	Medium likelihood to cause illness or injury in animals. Low likelihood in humans.

As with all examples, it should be emphasized that not all dog and cat food manufacturing facilities will have metal as a *hazard requiring a preventive control*.

Slide 43

The multi-species medicated and non-medicated animal food example on slide 5-35 showed how two facilities making the same types of animal food were controlling the same copper toxicity hazard in different ways. In that example, discussion focused on why the probability for the hazard may be different in the two facilities. In this example, the probability for the hazard is held constant and the example instead illustrates how differences in severity may also affect the outcome of hazard evaluation. This example uses metal as the hazard.

Both example Food Safety Plans identified metal as a *known or reasonably foreseeable hazard*. Furthermore, the probability of hazard occurrence was similar (B – Medium) in both facilities. The difference comes when evaluating severity of illness or injury to an animal. The feed mill manufacturing multi-species medicated and non-medicated animal food determined that the severity of metal was IV – Very Low. The facility manufacturing dry extruded dog and cat food determined the hazard had a severity of II - Medium.

The difference in the determination is based on differences in the intended species for the animal food. For example, the livestock feed example had a lower severity because a 300-lb pig is unlikely to consume metal even if the hazard occurred in its food because of the way pigs sort their food while eating. If the animal food with metal was consumed, the resultant illness or injury to the 300-lb pig would likely be minor due to the size of the pig's stomach. On the other hand, a small dog, such as a Chihuahua, is more likely to consume the metal hazard in its pet food due to its eating behavior by wolfing. If the small dog were to consume the same size metal hazard as the pig, the family pet is at greater risk to have severe injury, such as an intestinal blockage, than the 300-lb pig due to the Chihuahua's significantly smaller stomach. The difference in severity assessment was justification for the facility in each case to determine if a preventive control was or was not required. Again, these are just examples of ways that hazard identification and evaluation may be employed. Each facility is different, and it is the responsibility of the facility to consider a number of factors when identifying *known or reasonably foreseeable hazards* and then assessing their severity and probability to determine if they require a preventive control.

Hazard Analysis and Preventive Controls Determination Summary

- The hazard analysis is the most important element of developing an effective Food Safety Plan
- Hazard analysis includes identification, evaluation (for both severity and probability), and determination of control measures
- Outside resources are often needed to identify appropriate hazard analysis and control
- Hazard analysis is specific to the product and process



Slide 44

In summary, the hazard analysis is the most important element of developing an effective Food Safety Plan. The hazard analysis must include identification of known or reasonably foreseeable hazards, hazard evaluation (for both severity of illness or injury to humans or animals and the probability of occurrence), and the determination of appropriate preventive control measures to significantly minimize or prevent the hazard. Outside resources are often needed to conduct an effective hazard analysis and determine the appropriate preventive control(s). Finally, hazard analysis is specific to the product and process. The examples from this chapter are intended to demonstrate the complexities of the decision-making process and possible variations from one product to another and one facility to another. Hazard analysis and preventive controls determination is one of the key responsibilities of the preventive controls qualified individual. The next chapter will discuss the management components associated with preventive controls.

NOTES

PUBLIC VERSION

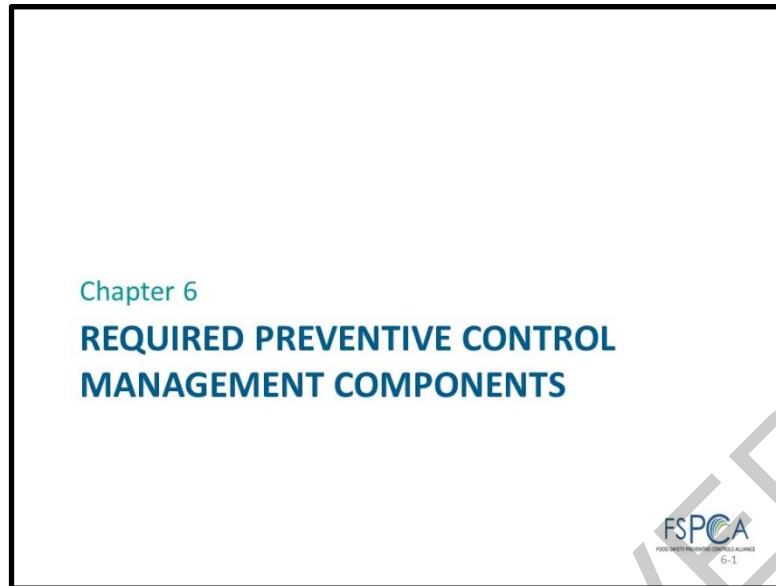
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

CHAPTER 6. Required Preventive Control Management Components



Slide 1

While the previous chapter helped describe the process for conducting the hazard analysis and determining which hazards require a preventive control, this chapter will discuss the required management components to ensure that those preventive controls are effective. The preventive control management components are listed in 21 CFR 507.39, which can be found on page 56347 of Appendix I. This chapter refers to multiple sections of the regulatory text, so it is important to follow along in the *Preventive Controls for Animal Food* rule. For example, the section on verification requirements is 21 CFR 507.45, but that section also refers to other requirements in 21 CFR 507.47, 507.49, and 507.55.

Required Preventive Control Management Component Objectives

In this module, you will learn:

- Components required to manage preventive controls
 - Monitoring – 21 CFR 507.40
 - Corrective actions and corrections – 21 CFR 507.42
 - Verification – 21 CFR 507.45
 - Validation – 21 CFR 507.47
 - Verification of implementation and effectiveness – 21 CFR 507.49



Slide 2

In this chapter, participants will learn the requirements for monitoring, taking corrective actions or corrections, and verification. Verification includes the concepts of validation and verification of implementation and effectiveness of the Food Safety Plan. The preventive control examples from the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds will be used as an example in this chapter to illustrate the concepts and outline the required preventive control management components.

21 CFR 507.39 Preventive Control Management Components

- (a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:
 - (1) Monitoring in accordance with § 507.40
 - (2) Corrective actions and corrections in accordance with § 507.42; and
 - (3) Verification in accordance with § 507.45.



The concepts of how facilities may apply these management components are explained in detail throughout the rest of the curriculum, particularly in Ch. 7, 8, and 9.

Slide 3

The rule requires that a *hazard requiring a preventive control* have components to manage the preventive control. Those management activities include monitoring the preventive control as required by 21 CFR 507.40, corrective actions and corrections as required by 21 CFR 507.42, and verification as required by 21 CFR 507.45. The associated definitions and requirements of these activities will be introduced in this chapter, with more details for application provided in subsequent chapters.

21 CFR 507.39 Preventive Control Management Components

- *(b) The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:*
 - *(1) Corrective actions and corrections with § 507.42, taking into account the nature of any supplier non-conformance;*
 - *(2) Review of records in accordance with § 507.49(a)(4)(ii); and*
 - *(3) Reanalysis in accordance with § 507.50.*
- *(c) The recall plan in § 507.38 is not subject to requirements of paragraph (a) of this section..*



Slide 4

This is the remainder of the regulatory text for 21 CFR 507.39. The balance of the chapter will explore the requirements in more depth. The supply-chain program does have required management components, but they are not clearly called out in this section of the regulation. Those management components are described more fully in Subpart E and will be described in Chapter 9: Supply-Chain-Applied Controls.

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

Reanalysis of the Food Safety Plan and a Recall Plan are also required, and are described in Chapters 4, and 10, respectively.

Slide 5

This table is a summary of the preventive control management components that are required to ensure the effectiveness of different types of preventive controls.

Process preventive control: The management components for process preventive controls are listed first. These components are described in more depth in Chapter 7. The required preventive control management components are monitoring, corrective actions and corrections, validation, and verification of implementation and effectiveness.

Sanitation preventive control: The next column lists the management components for sanitation preventive controls. Examples of these management components are described in more depth in Chapter 8. The required components are monitoring, corrective actions and corrections, and verification of implementation and effectiveness. Validation is not required for sanitation preventive controls.

Supply-chain-applied preventive control: The management components for supply-chain-applied controls are listed in column three. The specific examples of these management components are covered in Chapter 9. The only management component required by 21 CFR 507.39 for supply-chain applied controls is review of records. However, the Supply-Chain Program in Subpart E describes the requirements for the other management components, such as supplier verification activities and corrective actions taken in response to significant deficiencies identified during an audit or documentation of sampling and testing conducted as a supplier verification activity.

Other preventive control: Other preventive controls include procedures, practices, and processes as necessary to meet the requirements of part 507. Examples may include hygiene training and other current good manufacturing practices. The preventive control management components for “other controls” will depend on the nature of the control and the hazard it is controlling.

21 CFR 507.3 – Definitions: “Monitor”

- *To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.*



Slide 6

The first required preventive control management component is monitoring. The definition of monitor is *“to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.”*

In essence, monitoring involves the selection of appropriate measurements or observations at a specified frequency to provide information that is used to evaluate if a preventive control is meeting the parameters, such as a minimum or maximum value, that were set.

Parameter Value(s)

- Values (minimum and/or maximum) to which any biological, chemical, or physical hazard must be controlled to significantly minimize or prevent it.
- Associated only with monitoring Process Controls.



Slide 7

What to monitor and how frequently to monitor is determined by the type of preventive control. Monitoring can be associated with a parameter and a specified parameter value to ensure that the preventive control is working consistently. Parameter values will be discussed more fully in Chapter 7, but they are minimum and/or maximum values to which any biological, chemical, or physical hazard must be controlled to significantly minimize or prevent it. Parameter values are associated only with process controls.

21 CFR 507.40 Monitoring

- *As appropriate to the nature of the preventive control and its role in the facility's food safety system you must:*
 - *(a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and*
 - *(b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.*



A reminder: Monitoring is only a required management component for process controls and sanitation controls, not supply-chain applied controls because the monitoring occurs at the supplier's facility. This is described in Ch. 9.

Slide 8

Monitoring is required for process preventive controls and sanitation preventive controls. There is flexibility in how a facility can develop and design its monitoring system because conducting the activity may change as appropriate to the nature of the preventive control and its role in the facility's food safety system. A facility must have and implement written procedures for monitoring. These procedures must include how frequently the monitoring will occur. Monitoring must be completed on a frequent enough basis to ensure the preventive control is consistently working.

21 CFR 507.40 Monitoring

- (c)(1) You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with §507.49(a)(4)(i);
- (c)(2)(i) Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and
 - (ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.



Slide 9

The monitoring of preventive controls must be documented. Records associated with that monitoring are subject to the recordkeeping requirements of Subpart F, which was discussed in Chapter 1. In facilities that produce food for livestock animals, examples of these documents may include daily production records. Daily production records may be sufficient to meet the requirements of a monitoring record. Additional monitoring requirements are required for facilities that use cold storage or refrigeration to ensure that microbial growth is controlled. For example, a facility using cold storage would need to document the monitoring of the refrigeration temperature. Regardless of what is being monitored (such as daily production records or temperature), the monitoring activity is used to make sure the preventive control is working or detect a problem if the preventive control is not working.

<p>ABC Feed Mill 123 Street, Anywhere, USA</p> <p>SOP 200.6: Batching and Mixing – PC #2</p> <p>Purpose: Proper batching and mixing of ingredients is important to ensure accurate and consistent nutrient delivery to animals and prevent negative impacts on animal food safety.</p> <p>Frequency: Each run of feed</p> <p>Who: Batching operator</p> <p>Procedure:</p> <ol style="list-style-type: none"> 1. Prior to manufacturing feed, check scales are zeroed and mixer is empty per scale readout. 2. Confirm the feed to be manufactured is appropriate based on the sequencing plan. <ol style="list-style-type: none"> a. Prior to manufacturing sheep feed, a complete feed that does not contain a high copper premix must be manufactured, and a flush must be run prior to batching. 3. Confirm the formula to be batched is accurate based on the master record formula. 4. Weigh all ingredients during batching, document, record lot numbers where appropriate. 5. Mix for 90 s dry mix and 120 s wet mix times for total of 210 s. 6. Discharge the mixer to the correct finished feed bin, following appropriate sequencing. <p>Monitoring: Quantity of ingredient weighed during batching of each run, daily reconciliation of the following ingredients: sheep trace mineral premix, beef trace mineral premix, swine trace mineral premix, copper sulfate</p> <p>Corrective Action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the Food Safety Plan when appropriate.</p> <p>Records: Batching records, daily reconciliation records, corrective action records</p> <p>Verification of Monitoring and Record Review: Within 7 working days unless written justification is provided</p>	<p>Livestock Feed Example</p>
--	--------------------------------------

A “hand-add” is an ingredient that is weighed manually and added to the mixer by the operator. This is in contrast to an ingredient that is weighed and added to the mixer by an automated system.

This chapter and Ch. 9 use the example livestock feed safety plan to illustrate concepts, while Ch. 7 and 8 use the example pet Food Safety Plan.

Slide 10

Now that the requirements of monitoring have been described, the following example will be used to show how a facility may choose to employ procedures to meet those requirements. The Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds will be used to illustrate the requirements of monitoring for the required preventive control. The example used throughout this chapter will be Preventive Control #2, the weighing and addition of sheep mineral premix to ensure its accurate addition. This preventive control helps ensure that the correct ingredient is used to manufacture the animal food and that the correct amount of ingredient is utilized.

This example standard operating procedure (SOP) outlines the required steps for manufacturing an animal food intended for sheep. These steps include 1) checking scales are zeroed and the mixer is clean, 2) ensuring the previous diet manufactured did not contain a high level of copper, and 3) confirming the formula is accurate according to the master record formula. After the preliminary steps are completed, 4) the ingredients are weighed and that weight recorded. Lot numbers of ingredients, where appropriate, are recorded during this step. The ingredients are 5) mixed, and then the animal food is 6) discharged from the mixer. Step number 4 (weighing all ingredients and recording the weight) is the preventive control used as an example in this chapter. The next few slides will discuss the monitoring of this preventive control to ensure it is completed appropriately.

Example of Batching Record

ABC Feed Mill
123 Street, Anywhere, USA
Master Formula Batch Sheet
Date manufactured: 3-3-16 Sheep Diet – Non-medicated

Ingredient	Amount Required	Amount Added	Lot #	Batch Operator
Corn	1808	1809	Bin #2	CS
Alfalfa meal	300	305	Bin #1	CS
Soybean hulls	300	297	Bin #5	CS
Soybean meal	360	353	Bin #8	CS
Wheat	120	113	Bin #4	CS
Urea	15	15	7198	CS
Ammonium Chloride	15	15	74203	CS
Limestone	45	45	222016	CS
Sheep mineral premix	30	30	751237M	CS
Vitamin premix	7	7	751237M	CS
Total	3000	2989	n/a	CS

Verification of Reviewer Signature: Sue R. Quality Review Date: 3-5-16 6-11

Other monitoring records are needed to satisfy the other preventive controls for copper toxicity in the Example Food Safety Plan for Medicated and Non-Medicated Feeds. For example, Preventive Control #3 is the procedure for mixing and sequencing food for sheep to prevent toxic levels of copper from carryover from a previous animal food.

For Preventive Control #3, monitoring would involve documenting the previous batch manufactured. Oftentimes, daily production records from automation systems are appropriate to use as monitoring records for that type of preventive control.

Slide 11

In this example, monitoring Preventive Control #2 is accomplished by the reconciliation of designated ingredients. These include sheep mineral premix and ingredients that contain added copper, which for this facility include cattle mineral premix, swine mineral premix, and copper sulfate. The batch-to-batch and daily use of these four ingredients are reconciled to monitor the preventive control to ensure the correct volume of designated ingredients were used.

To accomplish the monitoring activity, the quantity of ingredient utilized will be recorded on batching records throughout the day. This slide presents an example of a batching sheet for an animal food intended for sheep. The quantity of sheep mineral premix added to each batch of animal food and the ingredient's lot number are recorded on the batching sheet. The batching operator, Chad Smith, has been assigned the responsibility for documenting the quantity of sheep mineral premix added to each batch and its lot number. The quantity and lot number of the sheep mineral premix is reconciled on a batch-to-batch basis to ensure the correct premix is used at the appropriate volume.

ABC Feed Mill 123 Street, Anywhere, USA	Livestock Feed Example
SOP 200.9: Daily Reconciliation of Designated Ingredients – PC #2	
Purpose: Reconciliation of theoretical and actual use of designated ingredients is necessary to ensure accurate and consistent nutrient delivery to animals and prevent negative impacts on animal food safety. Designated ingredients are: sheep trace mineral premix, beef trace mineral premix, swine trace mineral premix, copper sulfate.	
Frequency: Part 1: Each run of feed; Part 2: Daily	
Who: Batching operator	
Procedure:	
<ol style="list-style-type: none"> 1. Throughout the day: <ol style="list-style-type: none"> a. Record the quantity and lot number of designated ingredients used, sold, spilled or otherwise disposed throughout the day. b. Evaluate discrepancies throughout the day and investigate when appropriate. 2. At the end of the production day: <ol style="list-style-type: none"> a. Calculate total quantity of all designated ingredients used, sold, spilled or otherwise disposed of throughout the day (theoretical use) b. Conduct an inventory of all designated ingredients, regardless if they were used (actual use) c. Compare the actual daily disappearance of each ingredient (based on beginning versus ending inventories) to the anticipated daily theoretical use d. Calculate the percent deviation between theoretical usage and actual disappearance of the ingredients e. Report any deviation greater than 10% to a supervisor and investigate. 	
Monitoring: Theoretical use vs. actual use deviation; parameter: must be within 10%	
Corrective Action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the Food Safety Plan when appropriate	
Records: Batching records, daily reconciliation records, corrective action records	
Verification: Daily by Supervisor, within 7 working days by PCQI	

Slide 12

An SOP specific to daily reconciliation of designated ingredients was developed by the facility as another level of assurance that the correct premix was used during manufacturing. This process outlines the steps that must be completed by the batching operator to determine the inventory of designated ingredients. The SOP outlines that the batching operator will record the quantity and lot number of designated ingredients used, sold, spilled, or otherwise disposed of throughout the day. This allows him or her to evaluate if each batch of animal food in a run had the correct volume of ingredient added.

At the end of the production day, regardless if the designated ingredients were used or not used, the batching operator uses the batching records to calculate the theoretical quantity of designated ingredients used during the day. He or she then conducts an inventory by weighing and/or counting remaining bags of the designated ingredient to calculate the actual use during that day. The batching operator then calculates the percent deviation between theoretical and actual disappearance.


The SOP identifies that the parameter has been set at 10% between theoretical and actual use, so a deviation between theoretical and actual use greater than 10% of the volume of the difference between theoretical and actual use must be reported to a supervisor and investigated for appropriate correction or corrective action. These records are reviewed daily by the supervisor (as verification that monitoring is being conducted according to the facility's procedures), and the PCQI reviews them weekly.

**Example of
Designated Ingredient Reconciliation Record**

ABC Feed Mill
123 Street, Anywhere, USA
Date: 3-3-16 Copper Source Daily Reconciliation

Ingredient	Lot #	Start (lb)	End (lb)	Actual Use (lb)	Theoretical Use (lb)	Deviation (%)
Cattle TM premix	<i>CTM 456216</i>	38	38	0	0.0	0%
Swine TM premix	<i>STM 332016</i>	29	27	2	1.9	5.3%
Sheep TM premix	<i>STM 1237M</i>	133	102	31	30	3.3%
Copper sulfate	<i>CS122015</i>	45	45	0	0.0	0%

Verification of Reviewer Signature: Sue R. Quality Review Date: 3-8-16


FEDERAL SUPPLY PROGRAM FOR CATTLE, SHEEP, AND SWINE
6-13

Slide 13

This is an example of a monitoring record that may be used in the determination of theoretical and actual use of designated ingredients. The first column lists the ingredients that must be reconciled daily. Next, there is a blank area for the lot number of the ingredients to be documented. The third column is the inventory of these ingredients at the start of the manufacturing process. This should be the same quantity that was the ending inventory from the previous manufacturing day. The fourth column is the ending inventory of the ingredients at the end of the current manufacturing day. The difference between the third and fourth column are utilized to determine the actual use based on inventory of the ingredients, and is in Column 5. Next, Column 6 is the sum of the theoretical quantity of each ingredient utilized throughout the day, which is calculated from the batching records. Finally, in column 7, the deviation between the values is determined using the equation:

$$\text{Deviation} = \frac{(\text{actual use} - \text{theoretical use})}{\text{theoretical use}} \times 100$$

The SOP stipulates that any deviation greater than 10% between theoretical and actual use must be investigated. This monitoring record shows that all the designated ingredients were below this threshold.

21 CFR 507.42 Corrective Actions and Corrections

- (a) *As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:*
 - (1) *You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:*
 - (i) *The presence of a pathogen or appropriate indicator organisms in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and*
 - (ii) *The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).*



A description of when it is appropriate to use correction as compared to corrective action is in Chapter 8: Sanitation Preventive Controls.

Slide 14

If the deviation of one of the ingredients was greater than 10% in the previous example, a corrective action or correction may have been necessary. This leads to the second required preventive control management component, corrective actions and corrections. Requirements for corrective action and corrections apply to all types of preventive controls.

The rule states that, as appropriate, the facility must establish and implement corrective action procedures that must be taken if preventive controls are not properly implemented or when a pathogen or environmental pathogen is found. Additional information related to the application of corrective actions and corrections for different types of preventive controls will be discussed in Chapters 7, 8, and 9.

21 CFR 507.42 Corrective Actions and Corrections

- (2) The corrective action procedures must describe the steps to be taken to ensure that:
 - (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;
 - (ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;
 - (iii) All affected animal food is evaluated for safety; and
 - (iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.



Slide 15

Corrective action procedures must be written in the Food Safety Plan and must describe the corrective action procedures the facility will take if a failure of a preventive control or unanticipated food safety event occurs. The written corrective action procedures must describe how the facility will:

- Take appropriate action to identify and correct a problem that occurred with the implementation of a preventive control,
- Take appropriate action when necessary to reduce the likelihood that the problem will reoccur,
- Evaluate all affected animal food for safety, and
- Ensure that all affected animal food does not enter commerce if the facility cannot ensure its safety.

21 CFR 507.42 Corrective Actions and Corrections

- *(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:*
 - *(i) A preventive control is not properly implemented and a corrective action procedure has not been established;*
 - *(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or*
 - *(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.*



Slide 16

A facility must take corrective action in the event of an unanticipated animal food safety problem if any of the following circumstances apply:

- A preventive control is not properly implemented and a corrective action has not been established, or
- A preventive control or the Food Safety Plan is ineffective, or
- Review of records finds that the records are not complete, activities did not occur in accordance with the Food Safety Plan, or appropriate decisions were not made about corrective actions.

21 CFR 507.42 Corrective Actions and Corrections

- (2) *If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:*
 - (i) *Take corrective action to identify and correct the problem;*
 - (ii) *Reduce the likelihood that the problem will recur;*
 - (iii) *Evaluate all affected animal food for safety;*
 - (iv) *As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and*
 - (v) *When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.*



The requirement for corrective action procedures apply when a problem has been detected, regardless of whether the animal food has left the facility or not. If the animal food has entered commerce and there is a food safety concern because a failure of a preventive control has been identified, the facility must conduct a corrective action, as well as a recall.

Required components of a recall plan are listed in 21 CFR 507.38 and described in Chapter 10: Recall Plan.

Slide 17

In the event of an unanticipated animal food safety problem as described in the previous slide, the facility must:

- Identify the problem
- Fix the problem by taking steps to correct what went wrong
- Take action to make sure that the problem does not continually happen
- For any animal food that was impacted, determine if the food is safe
- Prevent the impacted animal food from entering commerce if it is adulterated
- Reanalyze the Food Safety Plan when necessary

Example of Batching Record

ABC Feed Mill
123 Street, Anywhere, USA
Master Formula Batch Sheet
Sheep Diet – Non-medicated

Date manufactured: 3-3-16 Operator: Chad Smith

Ingredient	Amount Required	Amount Added	Lot #	Batch Operator
Corn	1808	1809	Bin #2	CS
Alfalfa meal	300	305	Bin #1	CS
Soybean hulls	300	297	Bin #5	CS
Soybean meal	360	353	Bin #8	CS
Wheat	120	113	Bin #4	CS
Urea	15	15	7198	CS
Ammonium Chloride	15	15	74203	CS
Limestone	45	45	222016	CS
Sheep mineral premix	30	60	75237M	CS
Vitamin premix	7	7	752M1984	CS
Total	3000	3,019	n/a	CS

Verification of Reviewer Signature: Sue R. Quality Review Date: 3-5-16 6-18

Slide 18

An example of when a corrective action may be required using the previous example of Preventive Control #2 is shown here. The batching operator observed there was a significant discrepancy in the "Amount Required" and the "Amount Added" for the sheep mineral premix added to the batch. In fact, it appears that ingredient was potentially inadvertently added twice. The batch operator identified the discrepancy since the facility requires monitoring through batch-to-batch reconciliation of ingredients. Because of the inclusion of twice the sheep mineral pre-mix, a corrective action may be required to ensure the animal food is safe for sheep.

Corrective actions may include diverting the animal food to another species or blending the animal food until it has a safe level of copper for sheep. If this occurred, the facility should reanalyze the SOP and may need to retrain the qualified individual(s) to ensure that the batching operator knows and follows the SOP, including the addition of the appropriate ingredients at the right quantities to the animal foods.

**Example of
Designated Ingredient Reconciliation Record**

ABC Feed Mill
123 Street, Anywhere, USA
Copper Source Daily Reconciliation Operator: Chad Smith

Date: 3-3-16

Ingredient	Lot #	Start (lb)	End (lb)	Actual Use (lb)	Theoretical Use (lb)	Deviation (%)
Cattle TM premix	<u>CTM 456216</u>	38	38	0	0.0	0%
Swine TM premix	<u>STM 332016</u>	195	170	25	15	-40.0%
Sheep TM premix	<u>STM 1237M</u>	130	115	15	25	66.6%
Copper sulfate	<u>CS122015</u>	45	45	0	0.0	0%

Verification of Reviewer Signature: Sue R. Quality Review Date: 3-8-16

FSPCA
6-19

Slide 19

Another example of when a corrective action may be required is shown here. During daily reconciliation of designated ingredients, the batching operator observed there was a greater than 10% deviation between theoretical and actual use in swine mineral premix and sheep mineral premix. This process reveals that potentially an employee unintentionally included swine mineral premix in place of sheep mineral premix. This would not have been caught by a batching record, because the correct quantity of a premix was used, but the problem is that an incorrect premix was included in the sheep food. Using the incorrect mineral premix may cause copper toxicity in sheep, so corrective action is necessary.

21 CFR 507.42 Corrective Actions and Corrections

- (c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:
 - (1) You take action, in a timely manner, to identify and correct the conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or
 - (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.
- (d) All corrective actions (and, when appropriate, corrections) taken must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).



Slide 20

A facility does not need to comply with all the requirements for a corrective action discussed previously if action is taken in a timely manner to:

- Identify and correct the conditions and practices that are not consistent with sanitation controls; or
- Identify and correct a minor and isolated problem that does not directly impact product safety.

The regulatory text in 21 CFR 507.42(c) applies to circumstances of when a correction would be appropriate compared to a corrective action. A definition of the term *correction* is on the next slide.

The last requirement for corrective actions (and when appropriate, corrections) is that they be documented. These records are subject to verification to ensure appropriate decisions were made for the corrective action and records review to ensure appropriate decisions were made, records are complete, and that the corrective actions were done in accordance with the Food Safety Plan.

21 CFR 507.3 – Definitions: “Correction”

- *An action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).*



Slide 21

The definition of correction is “*An action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).*”

The difference between a correction and corrective action will be explained in greater detail in Chapter 8: Sanitation Preventive Controls. Think of a correction as something that can be done immediately to correct a problem to reduce the chance that an animal food with a food safety problem will enter commerce.

21 CFR 507.3 – Definitions: “Verification”

- *The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.*



Slide 24

The next preventive control management component is verification. The definition of verification is “the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the Food Safety Plan.”

21 CFR 507.45 Verification

- (a) *Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:*
 - (1) *Validation in accordance with § 507.47;*
 - (2) *Verification that monitoring is being conducted by §507.39 (and in accordance with § 507.40);*
 - (3) *Verification that the appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);*
 - (4) *Verification of implementation and effectiveness in accordance with § 507.49; and*
 - (5) *Reanalysis in accordance with § 507.50.*
- (b) *All verification activities conducted in accordance with this section must be documented in records.*



Slide 25

The requirements of verification are found in 21 CFR 507.45, which are found on page 56347 of the *Preventive Controls for Animal Food* rule in Appendix 1. This section cross-references with other preventive control management components.

There is flexibility in how a facility conducts verification activities. Where appropriate, verification activities must include:

- Validation of the preventive control
- Verification that monitoring is being conducted
- Verification that the appropriate decisions about corrective actions are being made
- Verification of implementation and effectiveness
- Reanalysis of the Food Safety Plan, which was described in Chapter 4.

Verification Key Concept

If it isn't written down,
you cannot prove that it happened.



FSPCA
NATIONAL CENTER FOR THE PROTECTION OF ABUSED CHILDREN
6-26

Slide 26

Verification is used to ensure that preventive controls are working as the facility intended. To verify, a facility will need to document. If the activity is not written down, a facility cannot prove that it happened. Written documentation of verification activities is required.

21 CFR 507.3 – Definitions: “Validation”

- *Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.*



Slide 27

The concept of validation is part of verification. This is a defined term in the *Preventive Controls for Animal Food* rule. Validation is “obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the Food Safety Plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.”

Verification vs. Validation

- | | |
|---|---|
| <ul style="list-style-type: none"> • Verification <ul style="list-style-type: none"> ▪ The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan. – 21 CFR 507.3 ▪ Are the preventive controls in the Food Safety Plan actually being properly implemented in a way to control the hazard? | <ul style="list-style-type: none"> • Validation <ul style="list-style-type: none"> ▪ Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards. – 21 CFR 507.3 ▪ Can the Food Safety Plan, when implemented, actually control the identified hazards? |
|---|---|



Slide 28

Both verification and validation are essential for an effective animal food safety system. Because they sound similar, they are easy to confuse. This slide summarizes their differences. Routine *verification* is an ongoing process to provide evidence that the Food Safety Plan is being properly implemented and operating as intended. In general, verification helps the facility answer the question: Are the preventive controls in the Food Safety Plan actually being properly implemented in a way to control the hazard?

Meanwhile, *validation* is the demonstration that following the Food Safety Plan will actually control the identified hazards. This concept helps the facility answer the question: Can the Food Safety Plan, when implemented, actually control the identified hazards? Thus, validation should be conducted prior to implementation of the Food Safety Plan, when appropriate.

21 CFR 507.47 Validation

- *(a) You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.*
- *(b) The validation of the preventive controls:*
 - *(1) Must be performed (or overseen) by the preventive controls qualified individual;*



Slide 29

The facility must validate that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system. The validation of the preventive control must be performed (or overseen) by the PCQI.

21 CFR 507.47 Validation

- (i)(A) Prior to the implementation of the food safety plan or;
- (B) When necessary to demonstrate the control measure can be implemented as designed;
 - (1) Within 90 calendar days after the production of the applicable animal food first begins;
 - (2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after first production of the applicable animal food first begins;



Slide 30

Validation must be performed (or overseen) by a PCQI. There are several situations when validation is required. Validation is required prior to the implementation of the Food Safety Plan. Validation is also required when necessary to show a preventive control can be implemented as designed, such as within 90 calendar days after the production of animal food first begins. If additional time is needed and the validation does not occur in the first 90 days, the PCQI must provide written justification for validation to occur in a reasonable timeframe.

21 CFR 507.47 Validation

- (ii) *Whenever a change to a control measure or combination of a control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and*
- (iii) *Whenever a reanalysis of the food safety plan reveals the need to do so.*
- (2) *Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.*



Slide 31

The next time validation is required is whenever there is a change to a preventive control that could impact the effectiveness of the control. Lastly, validation is also required whenever the reanalysis of the Food Safety Plan identifies the need for additional validation.

When validation is needed to show that a preventive control can be properly implemented, validation must include obtaining and evaluating scientific and technical evidence to determine whether the preventive control will effectively control the hazard. This technical evidence may be from scientific and technical reports. There may be situations in which that evidence does not exist. To get the necessary data, a facility may conduct in-house studies.

An example of using existing scientific and technical data can be seen in the pet food industry in the control of *Salmonella*. Scientific data demonstrates that pet food processed at 178°F (81°C) with moist heat (22% moisture) is adequate for instantaneous *Salmonella* destruction of 10⁶ log initial population. If this scientific data is referenced, it should be properly cited and understood by the PCQI. If scientific and technical data is used as part of the validation, that information must be maintained in accordance with the record-keeping requirements of subpart F.

In the livestock food industry, there may be a lack of scientific or technical data for the control of hazards. Furthermore, there are a wide variety of factors that change from one facility to another, such as ingredients, equipment, and process design. In this case, facilities manufacturing animal food for these species may need to rely on in-house studies and testing of processes to validate the effectiveness of a preventive control.

21 CFR 507.47 Validation

- (c) *You do not need to validate:*
 - (1) *The sanitation controls in § 507.34(c)(2);*
 - (2) *The recall plan in § 507.38;*
 - (3) *The supply-chain program in subpart E of this part; and*
 - (4) *Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that the validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.*



Slide 32

There are certain preventive controls that do not need to be validated. A facility does not need to validate sanitation controls, the recall plan, or the supply-chain program. Other preventive controls, do not need validation if the PCQI prepares a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

Information About Validation

- FSPCA website links to scientific information such as:
 - Peer reviewed scientific literature
 - Validated microbial modeling programs
 - Trade association guidance and white papers
 - Internal and external scientific studies
 - Cooperative extension websites for many universities



Additional links to relevant information will be added to the FSPCA website as they become available. As described in previous chapters, the appropriate control measures and parameters are specific to the type of animal food and its manufacturing environment. However, there is not available scientific and technical data for every situation. For example, there is limited data to describe necessary time × temperature combinations to destroy *Listeria monocytogenes* in pet food. In this case, scientific literature in human food may be appropriate.

Slide 33

Because scientific and technical data is required for validation, the Food Safety Preventive Controls Alliance has gathered links to information that may be relevant for animal food manufacturing facilities. Links to this data is available on the Alliance's website, such as peer reviewed scientific literature, validated microbial modeling programs, trade association guidance and white papers, examples of internal and external scientific studies, and links to the cooperative extension service websites for many land-grant universities.

Note that Preventive Control #2 (weighing all ingredients and recording the weight) used in the copper toxicity example is an example of a preventive control that does not have validation. The justification for not having validation is that the preventive control – procedures for ensuring correct manual weighing and addition of sheep mineral premix – does not have a possible validation because one cannot validate accurate hand addition with scientific or technical data. The facility should reference scientific literature that establishes maximum levels of copper for sheep food in their Food Safety Plan to set their parameter values, but the actual hand addition is not something that can be validated. Some preventive controls will not have validation because they cannot be validated. This is acceptable because the rule states, "...as appropriate to the nature of the preventive control and its role in the facility's food safety system." The other two preventive controls for copper toxicity (PC #1 and PC #3) in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds are examples of preventive controls that can be validated.

Summary of Validation

- Potential strategies
 - Using scientific principles and data
 - Conducting in-plant observations or tests
 - Guidance documents
- When validation is required
 - Before the Food Safety Plan is implemented (ideally) or
 - Within the first 90 days of production (unless justified)
 - When unexpected problems indicate the need for reanalysis
- Not required for supply-chain applied controls, sanitation controls, recall plan, but may be appropriate



Slide 34

In summary, the purpose of validation is to provide objective evidence that *process* preventive controls have a scientific basis and represent a “valid” approach to controlling the hazards associated with a specific product and process. This includes demonstrating that the equipment can deliver the process as designed and that the design parameters actually will control the hazard requiring a preventive control. Strategies that can be used to validate the Food Safety Plan include:

- using scientific principles and data from the literature
- relying on expert opinion
- conducting in-plant observations or tests at the limits of its operating controls
- using mathematical models
- incorporating regulatory guidelines

Because of the scientific concepts involved in validation, this element of preventive controls must be performed or overseen by a *Preventive Controls Qualified Individual*.

Validation must be done before implementing a preventive control identified in the Food Safety Plan, there is a change to the manufacturing process, or there is a problem that causes an evaluation to see if the preventive control is effective.

Validation is not required for supply-chain-applied controls, sanitation controls, or other preventive controls (if justified by the PCQI). A facility is also not required to validate the recall plan.

21 CFR 507.49 Verification of Implementation and Effectiveness

- (a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:
 - (1) Calibration of process monitoring and verification instruments (or checking them for accuracy);
 - (2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;
 - (3) Environmental monitoring if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and



Slide 35

In addition to validation, another component of the required verification of preventive controls is verification of their implementation and effectiveness. This is a required management component of all preventive controls. The concept is that the facility must verify that the preventive control(s) identified in the Food Safety Plan are being consistently applied and that they significantly minimize or prevent the hazard.

Examples of verification of implementation and effectiveness activities include:

- Calibration of instruments (such as thermometers and scales) to ensure their accuracy
- Product testing (such as for pathogens or nutrient deficiencies or toxicities);
- Environmental monitoring (such as for *Salmonella* spp. or *Listeria monocytogenes*)

21 CFR 507.49 Verification of Implementation and Effectiveness

- (4) *Review of the following records by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:*
 - (i) *Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and*
 - (ii) *Records of calibration, testing (e.g., product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and*
- (5) *Other activities appropriate for verification of implementation and effectiveness.*



While 7 days is the listed requirement, there are acceptable exceptions for a longer review time. An extension beyond 7 working days requires justification and supporting documentation.

Slide 36

Additional examples of verification of implementation and effectiveness activities include

- PCQI reviewing records, such as those for monitoring and correction actions, within 7-working days after they were created, or a reasonable timeframe if justified by the PCQI; and
- Other activities deemed appropriate by the PCQI

Several types of verification activities may be necessary for each preventive control to ensure that the procedures used are effective. However, not all of the examples of verification of implementation and effectiveness activities are appropriate for all hazards. For example, environmental monitoring is usually not appropriate if a facility does not have a biological hazard that requires a preventive control. The activities that are conducted for verification of implementation and effectiveness should be appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system.


**Example of
Designated Ingredient Reconciliation Record**

ABC Feed Mill
123 Street, Anywhere, USA
Copper Source Daily Reconciliation Operator: *Chad Smith*

Date: 5-4-16

Ingredient	Lot #	Start (lb)	End (lb)	Actual Use (lb)	Theoretical Use (lb)	Deviation (%)
Cattle TM premix	<i>CTM 456216</i>	38	38	0	0.0	0%
Swine TM premix	<i>STM 332016</i>	29	27	2	1.9	5.3%
Sheep TM premix	<i>STM 1237M</i>	133	102	31	30	3.3%
Copper sulfate	<i>CS122015</i>	45	45	0	0.0	0%

Verification of Reviewer Signature: *Sue R. Quality* Review Date: 5-8-16

 6-37

The PCQI is responsible for reviewing records, but may designate an individual to conduct this activity as long as the individual conducting the verification is properly trained and the verification is still overseen by the PCQI such as through periodic spot checks of the records.

Slide 37

Using the previous example of Preventive Control #2 (weighing all ingredients and recording the weight) in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds, the verification activities require weekly review of the daily reconciliation sheet by the PCQI. As described previously, daily reconciliation of designated ingredients was a monitoring step for the preventive control. Verification to ensure the preventive control is working and to verify that monitoring is being conducted is the review of the monitoring record by the PCQI at the end of each week. The PCQI is required to review the records within 7 working days according to the regulation and according to the facility's SOP for daily recognition of designated ingredients. Therefore, if the PCQI is not available then the PCQI must designate an individual to verify the records or create written justification as to why the records will not be reviewed within 7 working days. Even then, the PCQI is responsible for the oversight of the records and verification process.

21 CFR 507.49 Verification of Implementation and Effectiveness

- *(b) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:*
 - *(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;*



Slide 38

The facility must establish and implement written procedures, such as standard operating procedures, for:


- Method and frequency of calibrating instruments
- Environmental monitoring
- Product testing

In animal food manufacturing facilities, the type of instruments that require calibration may vary. For example, pet food facilities utilizing extrusion as a kill step for biological hazards would calibrate thermometers and temperature gauges. Alternatively, other animal food manufacturing facilities would calibrate scales by semi-annual scale certification. Written procedures for these activities may already exist in the facility prior to their implementation in the Food Safety Plan. Oftentimes, the standard operating procedures used to conduct those activities are adequate for this management component.

The requirements for environmental monitoring are not covered in this chapter but are discussed in Chapter 8: Sanitation Preventive Controls. Requirements for product testing are described next.

21 CFR 507.49 Verification of Implementation and Effectiveness

- (2) *Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:*
 - (i) *Be scientifically valid;*
 - (ii) *Identify the test microorganism(s) or other analyte(s);*
 - (iii) *Specify the procedures for identifying samples, including their relationship to specific lots of product;*
 - (iv) *Include the procedures for sampling, including the number of samples and the sampling frequency;*
 - (v) *Identify the test(s) conducted, including the analytical method(s) used;*
 - (vi) *Identify the laboratory conducting the testing; and*
 - (vii) *Include the corrective action procedures as required by § 507.42(a)(1).*



Slide 39

To verify that a hazard is being significantly minimized or prevented by a preventive control, product testing may be appropriate. The use of product testing is usually most appropriate for biological hazards, but it may also be used to verify the implementation and effectiveness of other preventive controls, such as a preventive control to prevent a nutrient deficiency or toxicity. Product testing may be accomplished through a number of methods, including in-line or finished product analysis.

Regardless of the method, procedures for product testing must:

- Be scientifically valid
- Identify the appropriate microorganism or analyte. (For biological hazards, the test organism must be identified. For non-biological hazards, the appropriate analyte, such as copper, must be identified.)
- Specify the process for identifying samples, including their relationship to specific lots of products, such as using the lot number as part of the sample identification number
- Include sampling protocols with the number and frequency of sampling per lot of product
- Identify the type of test to be conducted, including the analytical method that will be used
- Identify the laboratory, which could be an in-house laboratory, that will conduct the test
- Include corrective action procedures if a problem is found through product testing

Examples of Types of Verification Procedures

- Process verification
 - Validation of effectiveness
 - Checking equipment calibration
 - Product testing
- Sanitation verification
 - Visual inspection of equipment
 - Environmental monitoring
- System verification
 - Food Safety Plan reanalysis
 - Internal audits



Slide 40

There are several types of verification activities and procedures, but requirements and application of verification activities depend on the facility, processes used, and other factors.

Validation is one type of verification activity. Validation (i.e., making sure that the process actually controls the hazard) is required for most process controls. Validation, when required, is preferably done before the plan is implemented.

Other elements of verification are typically ongoing procedures that may be regularly scheduled, such as calibration of equipment (e.g., the temperature monitoring device for the extruder) or record review (e.g., documenting the correct manufacturing sequence was used when manufacturing animal food intended for sheep). Some verification activities are done less frequently, such as in-process or end product testing or internal audits. As with validation, required verification activities vary depending on the facility and other factors. Regulatory inspections are yet another type of verification activity in which the inspector reviews the adequacy of the Food Safety Plan, determines if it is being properly implemented, and reviews records to see if parameters are continually met and corrective actions are adequate.

Summary of Verification Activities

- Documented Verification Activities
 - Validation of PC
 - In-house tests, scientific papers
 - Monitoring is being conducted
 - PCQI reviewed records (within 7 working days)
 - Corrective actions are being made as required
 - Documented corrective actions and corrections
 - Implementation and effectiveness
 - Calibration records, product testing, environmental testing



Slide 41

In summary, there are many components of verification, and those components must be documented. These requirements include validation of the preventive control, as appropriate, verification that monitoring and corrective actions are being conducted as necessary within 7 working days, and records of preventive control implementation and effectiveness, such as calibration records, product testing, and environmental monitoring.

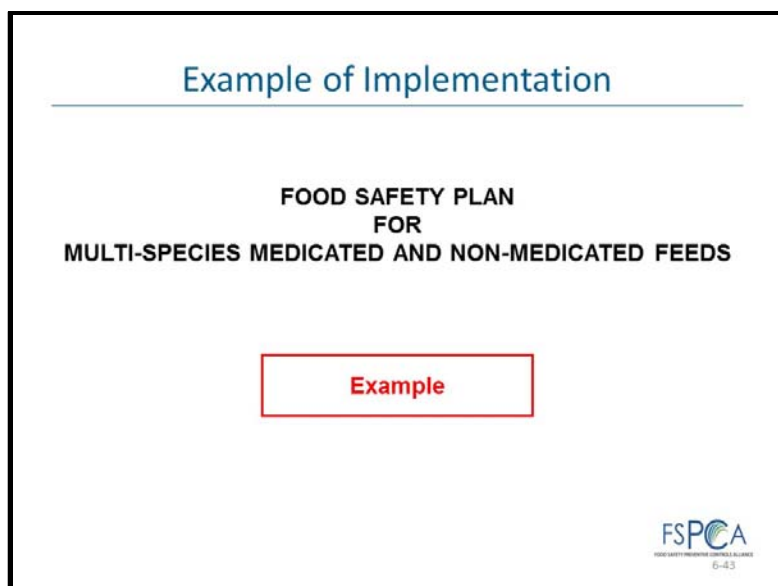
Summary of Required Preventive Control Management Components

- Preventive controls require monitoring, corrective actions and corrections, validation, verification, and verification of implementation and effectiveness.
 - Different types of controls may not require all preventive control management components.
 - The Preventive Controls Qualified Individual is responsible for oversight of the preventive control management components.



Slide 42

To close, preventive controls have required management components to ensure they significantly minimize or prevent hazards. These management components include monitoring, corrective actions and corrections, validation, verification, and verification of implementation and effectiveness. The PCQI is responsible for the oversight of these components.


**Slide 43**

As with Chapter 5, the next section describes one example of how a facility may choose to organize and document the preventive controls management components. We will continue to use Preventive Control #2 from the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Livestock Feeds as the hazard example. This is Table 2 and 3 in the example plan. This is also the format that will be used to describe the application of process preventive controls, sanitation preventive controls, and supply-chain-applied controls in Chapters 7, 8, and 9, respectively.

As with Table 1, color is used to denote different parts of Table 2. Green (columns 1 through 5) indicates the part of the table describing the preventive control, while purple (columns 6 through 8, Table 3) indicates columns that are specific management components for those controls.

Livestock Food Example				
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y	
PLANT NAME	ABC Feed Mill		ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls				
Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
Hazard Requiring a Preventive Control	Appropriate Control for Hazard Requiring a Preventive Control	Preventive Controls Number	Preventive Control Category	Parameters (if applicable)
Copper toxicity in sheep	Procedures for ensuring correct manual weighing and addition of sheep mineral premix	2	Process Control	10% deviation between theoretical and actual use



FOOD SAFETY PREVENTIVE CONTROL ALIANCE
6-44

Slide 44

The first set of columns in Table 2 are a summary of information determined in Table 1. These include the *hazard requiring a preventive control*, its appropriate preventive control, its preventive control number, and the type of preventive control. The procedures for ensuring correct manual weighing and addition of sheep mineral premix is preventive control #2, which is a process control. The next column provides an area to document parameters for the preventive control. Not all preventive controls will have parameters, but this preventive control includes the acceptable tolerance of a 10% deviation between the actual and theoretical use of designated ingredients.

Livestock Food Example				
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y	
PLANT NAME	ABC Feed Mill		ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls				
Preventive Control(s)	Management Components			
(1)	(6)			
Hazard Requiring a Preventive Control	Monitoring (if applicable)			
	What	How	Frequency	Who
Copper toxicity in sheep	Use of designated ingredients in each batch and throughout day	Reconciliation of designated ingredients: 1) Batching records; and 2) Daily actual vs. theoretical total use	Daily	Batching operator

Slide 45

In order to help participants follow along, Column 1 is shown again in this slide and the next slide. However, the description of the management components follows with Column 6, monitoring, which is separated into four different sub-columns.

The monitoring of the preventive control is to monitor the use of designated ingredients (added copper ingredients and sheep mineral premix) in each batch and over a single day. This will be accomplished through reconciliation of designated ingredients in batching records and total daily theoretical vs. actual differences for the designated ingredients. Reconciliation will occur for each batch and at the end of each day, and the monitoring activity is the responsibility of the batching operator.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 2. Description of Preventive Controls		
Preventive Control(s)	Management Components	
(1)	(7)	(8)
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records
Copper toxicity in sheep	If an incorrect quantity or premix was included: 1) identify root cause, 2) re-train employee(s) or re-calibrate equipment, as appropriate, 3) determine scope of problem by evaluating records and/or sampling and analyzing animal food, when necessary, 4) either blend, divert, hold-and-test, or dispose of affected animal food to prevent it from entering commerce, 5) reanalyze the Food Safety Plan, if necessary.	Batching records, daily designated ingredient reconciliation records, corrective action records, daily scale accuracy records, annual scale calibration


Slide 46

If monitoring reveals that the process control has failed – or in this case, the deviation between the theoretical and actual use of designated ingredients is greater than 10%, in theoretical use, a corrective action is necessary. If an incorrect quantity or premix was included, the facility's corrective action would be to: 1) identify root cause, 2) re-train employee(s) or re-calibrate equipment, as appropriate, 3) determine scope of problem by evaluating records and/or sampling and analyzing animal food, when necessary, 4) either blend, divert, hold-and-test, or dispose of affected animal food to prevent it from entering commerce, and 5) reanalyze the Food Safety Plan, if necessary.

In order to conduct these activities effectively, applicable documentation records include the batching records, designated ingredient reconciliation records, and corrective action records.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds	PAGE X of Y	
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 3. Description of Preventive Control Verification Activities	
Activity	Description of Activity
Type of Validation	n/a
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	Daily scale accuracy checks Annual scale calibration Product testing, when necessary
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.



FEDERAL SUPPLEMENTARY PROGRAM FOR ANIMAL FOODS
6-47

Slide 47

The final management component is verification. The monitoring and corrective action records will be reviewed within 7 working days by the PCQI or their designee of the documented action unless otherwise justified. There is no validation for this preventive control.

Finally, reanalysis of the plan is conducted every 3 years or as otherwise necessary. The Example Animal Food Safety Plan for Multi-Species Medicated and Non-Medicated Livestock Feed ends with a recall plan. A discussion of this plan is in Chapter 10: Recall Plan.

Now that participants have a clearer view of the hazard analysis and preventive controls determination, as well as the required management components for those preventive controls, the next few chapters will focus on the application of examples through different preventive controls.

NOTES

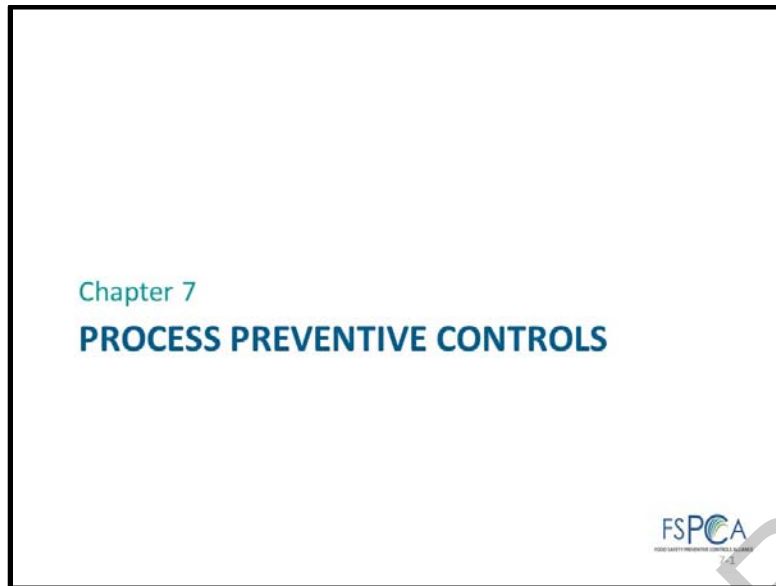
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

CHAPTER 7. Process Preventive Controls



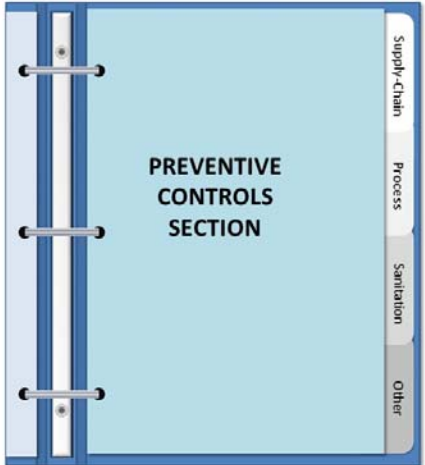
Slide 1

This chapter introduces process controls. These are controls that specifically relate to the procedures, practices, and processes within a facility.

Process controls make up the part of a facility's Food Safety Plan that focuses on controls required at process steps that are critical for the safety of the animal food. Process controls require documentation of parameters and minimum or maximum values associated with the control, monitoring procedures, corrective action procedures, and validation that the process controls the hazard.

The requirements for process controls depend on the role of the process control in the food safety system. This chapter provides information on establishing values for processing parameters, how to monitor process controls, and components of corrective actions to be taken for process controls when deviations occur.

Process Preventive Controls Objectives



- In this chapter you will learn:
 - The purpose and importance of process controls
 - How to apply relevant parameters and values associated with the process control
 - Monitoring procedures for process controls
 - Corrective actions for process control deviations

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
7-2

Slide 2

In this chapter, participants will learn 1) the purpose and importance of process controls, 2) how to apply relevant parameters and values associated with the process control, 3) monitoring procedures for process controls, and 4) corrective actions for process control deviations.

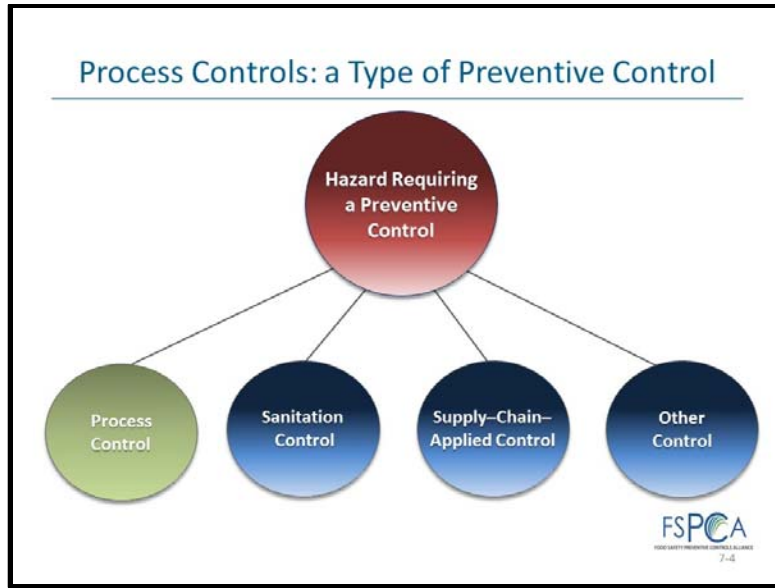
21 CFR 507.3 - Definitions: "Preventive Controls"

- Means those risk based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to **significantly minimize or prevent** the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.



Slide 3

As a reminder, preventive controls are specifically defined. Process controls, as well as all other preventive controls, are included under this definition.



The process for ensuring that a specified minimum temperature is maintained during extrusion, for the purpose of eliminating a potential pathogen, is an example of a written preventive control.

Documents demonstrating regular temperature checks and thermometer calibrations are examples of implementation records.

Slide 4

21 CFR 507.34 introduces preventive controls, and can be found on page 56345 of the *Preventive Controls for Animal Food* rule. This section explains that preventive controls are to be identified and implemented in order to significantly minimize or prevent any hazard that was identified in the hazard analysis as being a hazard requiring a preventive control. Preventive controls are required to provide assurance that the animal food manufactured, processed, packed, or held by a facility will not become adulterated.

Preventive controls are required at critical control points, as well as anywhere else that may be appropriate in order to ensure animal food safety. Some facilities or some class participants may be familiar with the concept of a critical control point, or CCP, if they have any experience with Hazard Analysis Critical Control Point (HACCP) plans. However, not all preventive controls may be critical control points. The hazard analysis process drives this determination.

All preventive controls must be written. These written preventive controls are documented in the Food Safety Plan. This includes a description of the process control and its management components such as parameters, monitoring, and corrective actions. Implementation records, which are records that document the implementation of the Food Safety Plan, are also required but are not the same as written preventive controls.

In addition to the process controls covered in this chapter, other preventive control categories include sanitation controls, supply-chain-applied controls, a recall plan, and other preventive controls which may not fall clearly into one of these categories. When selecting a preventive control, ensure that it is appropriate for the facility and the animal food.

21 CFR 507.34(c)(1) – Process Controls

- *“Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food.”*



Slide 5

Section 507.34(c)(1) specifically describes process controls as including, “procedures, *practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food.*” In this curriculum, the term “process preventive control” is used interchangeably with “process control” and both terms have the meaning specified in 21 CFR 507.34(c)(1).

Purpose of Process Controls

- To utilize procedures, practices, and processes to either significantly minimize or prevent a hazard in animal food.
- They allow the facility to establish specific parameters that must be met in order to assure that animal food safety is protected.
- Provide for evidence-based protection of animal food



Slide 6

The purpose of process controls is to utilize procedures, practices, and processes to significantly minimize or prevent hazards requiring a preventive control. Implementing a process control includes setting specific parameters that assure the production of safe animal food. Appropriately established parameters are those known to control the hazard(s) of concern based on scientific and/or technical evidence.

21 CFR 507.34(c)(1) – Process Controls

- *Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:*
 - i. *Parameters associated with control of the hazard; and*
 - ii. *The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.*



Throughout this curriculum, the term “parameter value” will be used. The definition for parameter value is taken from 21 CFR 507.34(c)(1)(ii). For purposes of this curriculum, a parameter value is “the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.”

Participants who have completed the human food course may identify a “parameter value” as being the same as a “critical limit.” The animal food curriculum chooses to use “parameter value”, which more closely follows the rule language.

Slide 7

21 CFR 507.34(c)(1) further goes on to specifically describe how parameters are to be identified and utilized. All process controls must include parameters associated with the control of the hazard.

These parameters must be appropriate for the control and its role in the food safety system. In other words, the identified parameters must have an impact on the control of the hazard. As such, adhering to the parameter values will significantly minimize or prevent the presence of the hazard in the animal food.

With this in mind, a maximum or minimum value, or potentially a combination of both, must be established for any parameter associated with a process control. Parameter values should be selected that result in the biological, chemical, or physical hazard being significantly minimized or prevented.

Parameter Value Example

Product	Hazard Requiring a Preventive Control	Preventive Control	Parameter Value Example*
Dog Food	<i>Salmonella</i> spp.	Extrusion temperature	Extrusion temperature $\geq 178^{\circ}\text{F}$ for instantaneous 6-log reduction

* Values are product dependent



In this example, the parameter value of 178°F is being considered the minimum temperature for instantaneous 6-log reduction of *Salmonella*. The effectiveness of most controls for biological hazards will assess their effectiveness in their ability to destroy pathogens. A 6-log reduction typically reduces pathogens below the threshold of detection by current analytical methods.

A process preventive control relying on a thermal parameter may also need to consider other items, such as time held at the temperature (if applicable) and the animal food matrix.

Slide 8

There are different types of parameters, and they must always be specific to the process control and the hazard being addressed. An effective parameter defines what can be measured or observed to demonstrate that the hazard is being controlled. For example, a temperature \times time combination may be the parameter value for a thermal processing step. For example, it may be determined that a dog food must be processed at a minimum temperature of 178°F for an instantaneous 6-log reduction of *Salmonella* during a thermal processing step, such as extrusion. In order to reach similar destruction, a lower extrusion temperature may require a longer time at that temperature. The time, temperature, and matrix are all interdependent upon one another to control the hazard.

Parameter Value Considerations

- If a pre-determined parameter value is not met, a hazard is effectively not under control, and the safety of the product is in question.
- Parameter values must be achievable.
- Often a variety of options exist for controlling a particular hazard.
- The selection of the best control option and parameter value is often driven by practicality and experience.



Slide 9

There are a number of considerations involved in establishing parameter values for a process control. A significant amount of thought, and often research, is necessary when setting these values because satisfying the parameter is essential in assuring product safety. Therefore, it is important that the parameter values are based on scientific or technical evidence and can be achieved by the process.

As a process may not realistically be able to maintain an exact value, parameters are often expressed as being equal to, above, or below a reference value. This allows the process control parameter to be met, and gives the option of varying from the exact reference value in order to be more conservative and limit any deviations. This is sometimes referred to as setting an “operating limit,” a concept that will be discussed later in the chapter.

Sometimes, different options can be applied to control a specific hazard, as it may be possible to control that hazard at various points within the manufacturing process. For example, a pathogen could be controlled during manufacturing, such as through thermal processing, or control can be applied at the end of manufacturing, such as through irradiation of the finished product.

The PCQI decides the best option, or combination of options, to control the particular hazard, taking into account practical considerations such as the process capabilities in question, how measurements can be made, staff capabilities and other appropriate factors.

Sources of Information for Parameter Values	
Information Source	Examples
FDA	Hazard guides; guidance, tolerance and action levels
Other regulation guidelines	State and local regulations, tolerance and action levels; USDA regulations
Experts (internal and external)	Preventive Controls Qualified Individual, processing authorities, university scientists, consultants, equipment manufacturers, sanitarians, trade associations
Scientific studies	In-house experiments, 3 rd party challenge studies (universities or contract labs)
Scientific literature	Peer reviewed journals, science and microbiology texts, Food Safety Preventive Controls Alliance information

Slide 10

A number of sources of scientific and technical information can be useful in establishing parameter values. FDA and other local, state, and federal government agencies may provide information through technical staff, regulations, guidelines, directives, performance standards, tolerances and action levels. Useful expertise may also come from both internal and external sources. Internally, this might include the PCQI, management, and experienced staff. Externally, information may be gathered from trade associations, process authorities, university and extension scientists, consultants, and equipment manufacturers.

If necessary, scientific studies for specific products can be conducted in-house, at a contract laboratory, or at a university. If a facility chooses to perform a study in-house, make certain to follow defensible methods in the experimental design and analysis.

Information can also be obtained from peer-reviewed scientific literature. However, there may be important differences between the methods used in a published study and those used for the animal food produced and processes employed by a facility. Therefore, care should be taken when using information from these sources to determine specific parameter values.

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

Slide 11

21 CFR 507.39 provides the management components that must be in place for a process control. The management components are used, as appropriate, to ensure the effectiveness of the process control. Process control management components include monitoring, corrective actions and corrections, verification, validation, and verification of implementation and effectiveness. The requirements for these management components were introduced in Chapter 6. The remainder of this chapter focuses on how these components will generally apply to process controls.

21 CFR 507.3 – Definitions: “Monitor”

- *To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.*



Slide 12

The definition of monitor is *“to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.”*

In essence, monitoring involves the selection of appropriate measurements or observations at a specified frequency. These measurements provide information that is used to evaluate if a process or procedure is meeting the parameters that were set.

Purpose of Monitoring for Process Controls

- To track the operation of the process and enable the identification of trends toward a parameter value that may trigger process adjustments.
- To identify when there is a loss of control or when a “deviation” from a parameter value occurs.
- To provide written documentation that can be used to verify that the process is under control.



Slide 13

The overall purpose of monitoring a process control is to document that a minimum or maximum value for a parameter has been met. Effective monitoring of all preventive controls ensures that food safety hazards identified in the Food Safety Plan are being controlled. If a parameter value has not been met, monitoring will identify the deviation, which will trigger the need for a corrective action.

Monitoring may also allow for the identification of a trend towards a maximum or minimum parameter value, allowing for adjustments to be made prior to a loss of control that would impact animal food safety. If adjustments are not made, monitoring will identify that a deviation from a parameter has occurred which indicates a failure in the preventive control. In this case, a corrective action is needed. Corrective actions are discussed later in the chapter.

Monitoring procedures must be specific to the process control and the identified hazard. This ensures that the monitoring provides data that can be used to establish a record demonstrating that the process is under control and that the animal food was produced in accordance with the Food Safety Plan.

Elements of Monitoring

1. What to monitor
2. How to monitor
3. Frequency to monitor
4. Who will monitor



Slide 14

Procedures for monitoring a preventive control must be documented in the Food Safety Plan. Procedures for monitoring process control should address four elements: 1) what measurements or observations will be used to monitor the parameter(s), 2) how will the monitoring be conducted, 3) how often will monitoring occur, and 4) who will do the monitoring. Adequate records specific to the preventive control and the hazard are to be generated to document monitoring activities. Monitoring records must be maintained by the facility in accordance with subpart F.

What Might Be Monitored?

Depends on process, examples include:

- Temperature
- Time
- Volume / weight
- Line speed
- Flow rate
- Bed depth
- Acid addition
- pH
- Water activity
- Chemical concentration
- Appearance
- Process performance



Slide 15

Monitoring process controls depends on the nature of the preventive control and its role in the facility's food safety system. Monitoring may involve measuring either a characteristic of the animal food or a part of the process itself. Examples of monitoring measurements include (but are not limited to):

- Animal food temperature as it passes through a thermal process used as a “pathogen heat-kill step.”
- Process parameters such as retention time, line speed, or flow rate if these have been validated to control the hazard either alone or in combination with a temperature measurement.
- Observing that the metal detector is on when metal is a hazard of concern.
- The volume or weight of an ingredient or finished food after production is complete.
- Animal food parameters such as pH, water activity, and nutrient composition.

Visually monitoring the animal food may also be useful, as this can be an indicator of a process failure. Visual monitoring could include observing the appearance of animal food. Based on these observations, additional evaluation may be necessary. Visual observations may provide indication that something is not working correctly with a preventive control; however, they may be most useful in detecting quality concerns with a product, such as color or pellet quality. As discussed in chapter 4, a quality issue may not necessarily constitute a food safety concern and may not result in a hazard requiring a preventive control.

How is a Process Preventive Control Monitored?

Examples May Include:

- Calibrated thermometer
- Calibrated pH meter
- Calibrated chart recorder
- In-line analyzer
- Real-time laboratory analysis
- Visual checks



Slide 16

Different methods can be used to monitor parameters associated with process controls.

There are a variety of monitoring instruments that can be used to measure parameters. A facility should ensure that instruments used to monitor a process control are properly calibrated. Examples of monitoring instruments could include thermometers, pH meters, chart recorders, scales, and many other devices.

In-line analysis can be a useful monitoring tool. An example of in-line analysis is metal detection, which is used to locate and isolate metal contamination.

Some rapid testing methods can be performed on site and can then be used for decision making. For example, pH measurements, moisture content, water activity, and other types of tests may have application in a Food Safety Plan. Lengthy analytical tests, such as biological assays, may also be useful for routine monitoring, but pose additional challenges. When such tests are used, test and hold procedures may be necessary to ensure the animal food is safe before it enters into commerce.

Monitoring methods can also involve visual checks. When using visual observation, appropriate parameter values should be selected so that it is clear whether or not the parameter has been violated. Visual checks may not always be suitable for monitoring of process controls, but can be used to ensure that necessary equipment is operating properly, and that the animal food has an appropriate appearance.

Equipment used for measurements must be checked to ensure the process preventive control is effectively monitored.

The calibration of monitoring devices is a verification activity used to ensure that the measurements taken by the monitoring device are accurate and reliable. More information about verification is described in 21 CFR 507.49.

Calibration involves comparison against a known calibrated instrument or standards. This ensures that the device is functioning correctly

More information on calibrations can be found on the National Institute of Standards and Technology website:
<http://www.nist.gov/pml/wmd/lab metrology/calibration.cfm>

Monitoring Methods

- Continuous
 - In-line systems
 - Chart recorders
- Non-Continuous
 - Batch basis
 - Visual observations
- Both methods require generation of monitoring records!



Slide 17

Monitoring frequency depends on the process control and the types of observations and measurements that are needed. Examples of continuous monitoring could include in-line systems or chart recorders. Individual measurements may also be taken or observations made on a less-frequent schedule. This could include testing a product on a per-batch basis or a visual check of a particular process once per shift.

Regardless of whether continuous or non-continuous monitoring is utilized, the frequency should be at regularly scheduled intervals, and a monitoring record must be generated. The monitoring must be appropriate for the animal food, the hazard, and the process control.

Continuous Monitoring Considerations

- Continuous monitoring is preferred
- Continuous monitoring examples
 - Temperature recording chart
 - Metal detector
 - In-line pH probe
 - Bar code scanner
 - Imaging system for foreign material



While continuous monitoring may be preferred, it is not required.

Continuous monitoring can be performed by a device itself as long as a visual check of the data and/or functionality is also performed to ensure that the device is functioning properly.

Charts run out of ink, pens get stuck, and probes can malfunction; this is why human involvement is necessary, at least periodically.

Continuous monitoring is not feasible in many cases due to cost, process flow, and/or available technology.

Slide 18

When possible, continuous monitoring procedures are generally preferred. This is because they reduce gaps in recording, as the equipment utilized doesn't forget to collect the data or generate the record. Continuous monitoring is generally performed by an instrument that produces a continuous record. For example, these records can be either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control.

When using continuous monitoring procedures, the record generated from the monitoring needs to be checked by a qualified individual periodically to ensure that the necessary parameters are being met and that the device is operating properly. The length of time between checks is determined by the facility. Keep in mind that the frequency of these checks will directly affect the amount of animal food impacted when a deviation occurs.

Examples of continuous monitoring could include:

- The time and temperature data for a continuous flow extrusion process that may be continuously monitored and recorded on a temperature-recording chart.
- A functioning metal detector that automatically monitors all product that passes through it.
- An imaging system that monitors the production stream, looking for any foreign material that must be removed.

Again, the proper functioning of equipment and any records generated for these types of systems must be monitored by a qualified individual on a pre-determined basis to document that the system is performing as specified in the Food Safety Plan and that deviations have not occurred.

Non-Continuous Monitoring Considerations

- Used when continuous systems are not feasible
- Frequency of non-continuous monitoring
 - How much does the process normally vary?
 - How close are the normal operating values to the parameter values?
 - How much product is at risk if the process becomes out of tolerance?
- Non-continuous monitoring examples
 - Temperature checks at specified intervals
 - Inventory of a potentially toxic ingredient



Slide 19

Because continuous monitoring is often infeasible, non-continuous methods are often chosen to monitor process controls.

It is necessary to establish a monitoring interval that ensures that process parameters are met. The frequency of non-continuous monitoring could be influenced by historical knowledge of the animal food and process. Questions that could help determine the frequency include:

- How much does the process normally vary (e.g., how consistent are the data)? If the monitoring data show a great deal of variation, the time between monitoring checks should be short.
- How close are the normal operating values to the parameter values? If the normal values are close to the maximum or minimum allowed value, the time between monitoring checks should be short.
- How much animal food is at risk if a deviation occurs? If a large amount of product is at risk and cannot be reworked, for example, more frequent monitoring may be prudent.

Examples of non-continuous monitoring might include temperature checks of a thermal processing step at specified intervals, or recording the inventory of a potentially toxic ingredient at the end of each production shift.

Exception Records

- Exception records are generated only when a limit is not met; e.g.,
 - Cooler records when temperature goes above a set limit
 - X-ray that responds only to foreign material
- Often an alarm alerts the operator of a problem
- Exception record systems must be validated



Exception records are a new concept in the regulation.

Validation is required for exception record systems.

Slide 20

Exception reporting involves automated systems that are designed to alert operators and management only when a deviation (in other words an exception) from the requirement is observed. Automated exception reporting may be more efficient than that performed by operators, which allows for an increase in the frequency of monitoring, which is typically accomplished through continuous monitoring, and reduction of human error.

For example, refrigeration temperature control can notify on exception (e.g., high temperature alarm) and may only record temperatures that exceed the specified temperature. Such systems must be validated and periodically verified to ensure they are working properly. With such systems, monitoring records may not always be necessary, when validation and periodic verification are conducted to ensure that the system is working properly. Therefore, records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled (e.g., a chart recorder) or exception records demonstrating loss of temperature control (e.g., an alarm system that records when a deviation occurs).

If a facility uses “exception records,” the facility must have evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an “exception record” is generated. Exception records may also be adequate in circumstances other than monitoring of refrigeration temperature, such as monitoring for foreign material with x-rays, which results in a record only when the system detects foreign material. Validation is required.

Who May Monitor?

- Trained, designated, qualified individual
- May not necessarily be quality assurance (QA) staff; can be other employee(s):
 - Operators
 - Supervisors
- Considered a best practice for monitoring to be done by an individual other than the one who verifies records



Individuals who conduct monitoring activities must meet the definition of being *Qualified Individuals*.

Small facilities may have a limited number of people available for monitoring and record review. Thus, a small company may have the same person fill out the monitoring record and also review the record. This may not be ideal, but may be necessary.

Slide 21

Individuals assigned to monitoring activities should be trained and designated to perform the activity, and must meet the definition of a qualified individual. These individuals may be members of the quality assurance team, but could also be line personnel, equipment operators, supervisors, maintenance personnel, or other qualified staff.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously watching the animal food or equipment. Including production workers in food safety activities helps build a broad base of understanding and commitment to the preventive controls program and a facility's food safety culture.

The qualified individual (who is responsible for monitoring) should respond immediately to all deviations and report them as necessary. This will ensure that process adjustments and corrective actions are made in a timely manner.

All records and documents associated with preventive control monitoring must be signed or initialed by the person doing the monitoring activity, be dated, and, where appropriate, include the time of the monitoring activity recorded.

It is considered good practice for the person doing the monitoring and the person responsible for record review to be different so that errors are not overlooked. However, this is not required, and may be unavoidable in some instances. Also, verification is required to ensure that monitoring is being conducted in accordance with your monitoring procedures. This could be done through someone observing a qualified individual conducting monitoring or through a review of monitoring records, such as the monitoring record review required to be done by (or under the oversight of) a PCQI.

Qualifications for Monitoring Individuals

- Trained in monitoring techniques through on-the-job or other appropriate training
- Should fully understand the importance of monitoring
- Must be able to accurately report each monitoring activity
- Should understand actions to take when deviation occurs
 - Immediate corrective actions related to the process
 - Timely reporting of the deviation(s)



Slide 22

Properly trained (“qualified”) personnel must be available at all times that the process control requires monitoring. While monitoring activities may be assigned to a supervisor, make sure this is realistic for the facility. For example, supervisors are sometimes called away for other activities, such as accompanying an inspector during an inspection visit. It is not realistic to expect one person to accompany an inspector and perform monitoring activities at the same time. With this in mind, it is a good practice for monitoring to be conducted by operators who are present at all times during production. The importance of monitoring procedures should be fully explained, and the individual should be trained in the appropriate techniques. In order for the monitoring to be effective, the individual must be able to accurately document the monitoring activity.

A facility may choose to allow the individual responsible for monitoring to take immediate action when a deviation occurs. For example, this could include investigating the cause, documenting any findings, or even shutting down the process without direct involvement from supervisors. Even if a facility chooses not to allow the individual responsible for monitoring to take these actions in the event of a deviation, they should still be aware of what actions may need to be taken and should understand that timely reporting is key.

21 CFR 507.42 Corrective actions and corrections

- Corrective actions procedures must be established to address situations where preventive controls are not properly implemented.
- As appropriate, procedures must be in place to address the presence of pathogens or appropriate indicator organisms.
- Corrective action procedures, when followed, will ensure that:
 - Problems are identified and corrected
 - The likelihood of problem recurrence is reduced
 - All affected animal food is evaluated for safety and does not enter into commerce if it may be adulterated.



One specific example of when corrective action procedures are required is when pathogens or appropriate indicator organisms are present (21 CFR 507.42(a)(1)(i)). Two key biological hazards of concern that may require corrective action or correction are *Salmonella* spp. and *Listeria monocytogenes*.

While this is one situation in which corrective action procedures are required, this is not the only instance that requires corrective action.

Slide 23

Corrective actions must be established for process controls. The requirements for corrective actions and corrections are discussed in 21 CFR 507.42 of the rule, which can be found on page 56347 of the *Preventive Controls for Animal Food* rule. The purpose of these procedures is to fix problems with the implementation of preventive controls, and prevent further instances of the identified failure. When something goes wrong, corrective actions or corrections must be performed depending on the hazard, the nature of the preventive control, and the deviation that has occurred.

The rule requires that if a pathogen has been identified as a hazard requiring a preventive control, corrective action procedures must be in place to address its presence. Alternatively, procedures can address the presence of an appropriate indicator organism, if it is detected through product testing or environmental monitoring. Corrective action procedures must be written in the Food Safety Plan and must describe the actions the facility will take if there is a failure in a preventive control. The written corrective action procedures must describe how the facility will:

- Take appropriate action to identify and correct a problem that occurred with the implementation of a preventive control,
- Take appropriate action when necessary to reduce the likelihood that the problem will reoccur,
- Evaluate all affected animal food for safety, and
- Ensure that all affected animal food does not enter commerce if the facility cannot ensure its safety.

If a corrective action is needed, the facility must take action to:

- Identify the problem
- Fix the problem by taking steps to correct what went wrong
- Take action to make sure that the problem does not continually happen
- For any animal food that was impacted, determine if the food is safe
- Prevent the impacted animal food from entering commerce if it is adulterated
- Reanalyze the Food Safety Plan when necessary

Corrective Actions for Process Controls

- Executed when a process control is not properly implemented.
 - E.g. there is a deviation from a maximum or minimum allowed parameter value
- Possible animal food safety issue may have occurred and/or an unsafe product may have been produced.
- Must be developed in advance for each process control and be included in the Food Safety Plan.



The extent of corrective action depends on a number of factors. If there is repeated failure to meet a parameter value, then specific training, equipment repair, or other corrective action may be necessary to resolve the issue.

If the root cause of the deviation involves many systems in the facility, revalidation of the entire food safety system may be needed. This might happen if a major maintenance event, such as construction, has resulted in contamination from unknown points.

Slide 24

The need for corrective action arises when a process control is not properly implemented. For instance, a corrective action would be required when there is a deviation from an established maximum and/or minimum parameter value.

A corrective action is necessary any time such a deviation occurs, regardless of whether or not the facility feels that an unsafe animal food has been produced. In other words, corrective actions are independent of perceived food safety. In some cases, where a corrective action is required, it may be possible to evaluate the food and make a determination that it is safe. In this case, the corrective action may not necessarily require the disposal of the animal food. However, something must be done to determine why the failure occurred and how it can be prevented in the future.

All corrective action procedures must be developed in advance and be documented in the Food Safety Plan.

Corrective Action Considerations for Process Controls

- Corrective actions must be:
 - Specific to the process control
 - Immediate and comprehensive
- Corrective actions must include:
 - Identifying the implicated product
 - Determining the disposition of non-compliant animal food
 - Correcting the cause of the non-compliance
 - Determining that the process is once again under control



When determining the disposition of any non-compliant animal food product, there should be some explanation of the rationale used in estimating the impact of the non-compliance.

Slide 25

The Food Safety Plan is to be designed to ensure that failures of a process control are rapidly identified and corrected. Predetermined corrective actions provide a “how-to” guide that describes the steps that need to be taken when a preventive control is not properly implemented. The duty of carrying out these procedures must be assigned to one or more qualified individuals who have a thorough understanding of the operation, the animal food(s), and the facility’s Food Safety Plan and who have the authority to make decisions.


Corrective actions are to be developed for each process control, considering all of the types of deviations anticipated. For example, assuming a control relies on time and temperature to ensure sufficient pathogen destruction, deviations could occur for either the time or the temperature parameter. Corrective actions would need to be in place to address both possibilities. The timing for corrective actions depends on the monitoring frequency. Corrective actions need to be initiated as soon as the deviation is identified, and must encompass all animal food that could have been affected by the deviation.

When a deviation is detected, the first action is to identify the animal food involved. Implicated product should be segregated and evaluated to determine if a food safety hazard exists. If a hazard exists, the affected animal food must be reworked or destroyed.

Control of the process must also be restored. A corrective action should take care of the immediate problem, as well as provide long-term solutions to reduce the likelihood that the problem will recur. The objective is to re-establish control of the process so that production can start again without further deviations. This may involve equipment repair, employee training and overall evaluation of the process for improvements.

Corrective Action Examples

Process Examples	Product Examples
<ul style="list-style-type: none"> • Immediate adjustment of process • Employees stop line when deviation occurs • Apply alternative process • Repair equipment • Retrain employees • Evaluate operation 	<ul style="list-style-type: none"> • Hold product • Evaluate product • Determine product disposition <ul style="list-style-type: none"> ▪ Release, rework or destroy product



In some situations, an animal food may be “cleared” to move off-site, but be put on hold there until the deviation is resolved. This may apply to facilities with limited on-site warehousing.

Slide 26

Examples of corrective actions for process controls include those listed here. Sometimes an immediate adjustment of the process can be used to address an out-of-control event. In other cases, an immediate adjustment during processing may not be a feasible solution. An example of this might be a batch process where in- and out-of-control animal food cannot be separated.

As previously mentioned, it may be appropriate for an employee to stop the line. This requires empowerment of the employee to take the action.

In some situations, an alternative process may have been validated to be effective at controlling the hazard. If this is the case, such a process may be implemented as a corrective action. For example, if a temperature drops below the parameter value, an alternative process that involves longer time at a lower temperature may be applied, provided it has been validated.

Other examples of corrective actions might include equipment repairs, or retraining employees on proper procedures. In some situations, an evaluation of the entire operation may be required to ensure that the operation is capable of producing the animal food under conditions that are essential for animal food safety.

When a deviation from required parameters occurs, however brief, corrective actions are to include an evaluation of all affected animal food for safety. The affected animal food must be evaluated for safety prior to determining the appropriate disposition.

Pet Food Example	
Corrective Action Form	
PLANT NAME: ABC Pet Food Company	
ADDRESS: 123 Street, Anywhere, USA	
Product Name:	Code or Lot Number:
Date of Record:	
Date and Time of Problem:	
Description of Problem and Root Cause:	
Actions Taken to Correct the Problem:	
Person Taking Action (name and signature) :	
Amount of Product Involved in Problem:	
Evaluation of Product Involved with Problem:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date:

Slide 27

This is an example of a Corrective Action Form, which a facility may choose to include in its Food Safety Plan. In some situations, corrective action activities may take place in a short period of time. In other more complicated situations, corrective action activities may take place over several days. It is important to have an accurate record of all corrective actions in order to assure that the animal food is safe and so that the PCQI can review records to ensure that appropriate decisions were made for the corrective action. For example, failure to adequately document when the incident started and ended can lead to an expanded recall affecting a substantial amount of animal food that would otherwise have been unaffected. Keep in mind this adage: if you don't write it down, it never happened.

Operating Limits

- Criteria that are more stringent than parameter values and that are used by an operator to reduce the risk of a deviation.
- Operating limits may be established:
 - For quality reasons
 - To avoid deviating from maximum and/or minimum allowed parameter values
 - To account for process variability

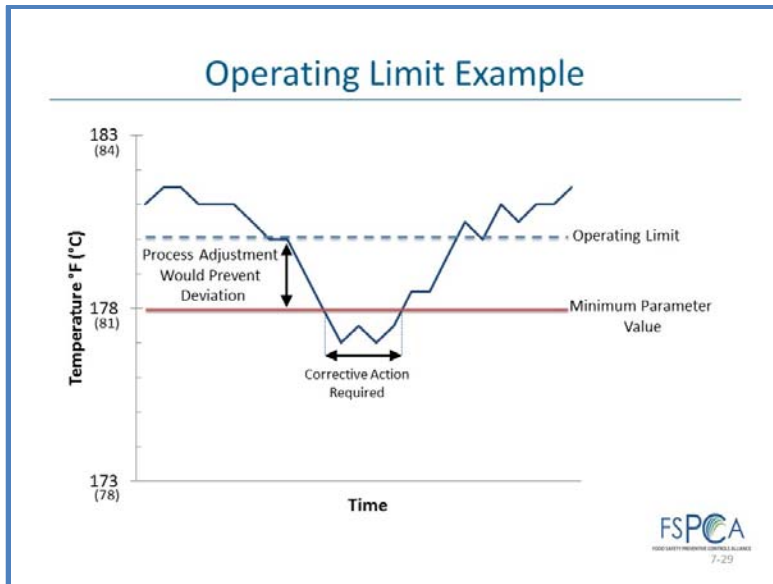


Slide 28

The use of an operating limit may allow for the detection of a potential problem before a process control deviation. This is because the value for the operating limit can be more conservative than the minimum or maximum established parameter values. The process may be adjusted when the operating limit is not met but is still within the established parameters, thus avoiding the need to take corrective action. Operating limits are not required by the rule, but are a good example of a tool that may be used alongside a process control.

Operating limits may be established:

- For quality reasons – for example, higher final temperatures than are needed to kill pathogens may enhance the physical properties of the animal food.
- To avoid deviating from maximum and/or minimum allowed parameter values; or
- To account for normal variability – for example, any batching process will have some variation in weight; an appropriate operating limit can warn operators if the process is approaching a deviation amount that would be considered out-of-control.



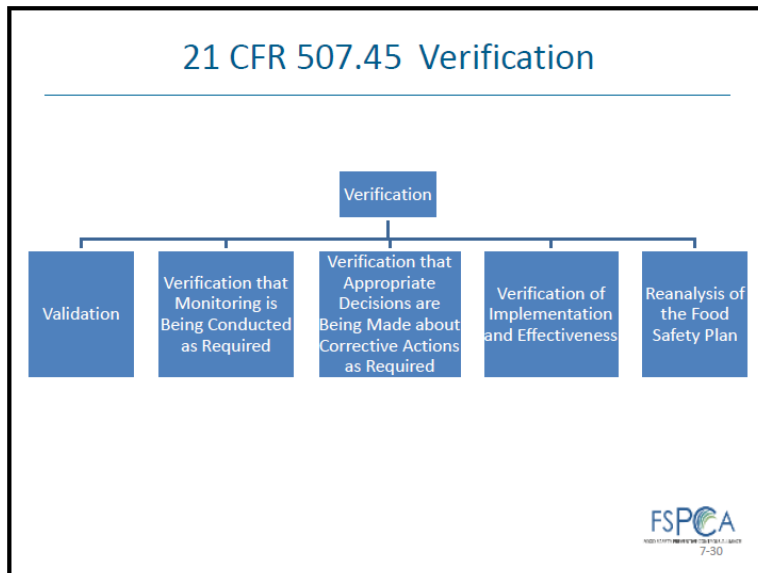
Slide 29

The example above illustrates two important points:

- 1) Operating limits and process adjustments, and
- 2) Parameter values and corrective actions

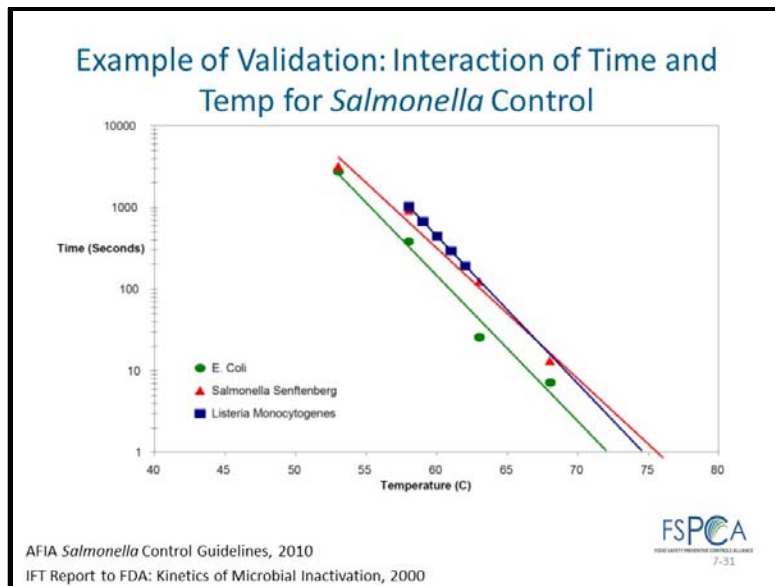
In this example of a cooking process, a minimum parameter value is established at 178°F (81°C). In the slide, the temperature of the process fell below the minimum value.

The facility in this example chose not to set an operating limit. Setting an operating limit (180°F (82°C)) above the minimum value could have alerted an operator to make a process adjustment to bring the temperature back above the operating limit prior to the temperature going below the set minimum parameter value. If an adjustment is made before the temperature drops below the minimum parameter value, no corrective action would be required. However, in this example, an adjustment was not made until after the temperature dropped below 178°F (81°C), thus appropriate corrective actions must be taken and a corrective action record must be generated.

**Slide 30**

In addition to monitoring and corrective actions, verification is a required management component for process controls. Verification is used to make sure that preventive controls are working as the facility intended to control a hazard. Verification includes validation of the chosen control to assure that it is capable of significantly minimizing or preventing the identified hazard requiring a preventive control. The next slide will discuss an example of validating a process control.

There must be verification that monitoring is being conducted, that appropriate decisions about corrective actions are being made, and that the control is being consistently implemented and is effective in addressing the hazard. A facility must be able to verify that reanalysis of the Food Safety Plan is being conducted as required by the rule, meaning at least once every 3 years and as appropriate when there is a significant process change, new information about a hazard becomes available, or a food safety failure occurs. As with all preventive control management components, these verifications must be documented in records.



Slide 31

Scientific data may be used to demonstrate how a chosen preventive control is capable of significantly minimizing or preventing a hazard. This slide is an example of scientific data that a facility could use to validate their manufacturing process.

The chart, which is from the American Feed Industry Association's *Salmonella* Control Guidelines and is data derived from a report from the Institute of Food Technologists, illustrates the time and temperature combination at which there is a 6-log reduction in *E. Coli* (green circles), *Salmonella Senftenberg* (red triangles), and *Listeria monocytogenes* (blue squares). This example only focuses on the data related to *Salmonella Senftenberg* (red triangles). The x-axis is the temperature in Celsius, while the y-axis is a logarithmic scale of time in seconds.

As the temperature increases, the length of time required for a 6-log reduction of the hazard is reduced. For example, a 10^6 -log reduction of *Salmonella Senftenberg* requires approximately 1,000 s, or over 16.5-minutes, of thermal processing time when processed at 58°C. (136.4°F) Alternatively, the same 10^6 -log reduction of the hazard requires approximately 10 s of thermal processing time when processed at 68°C (154.4°F). This line can be extrapolated to predict a 10^6 -log reduction can occur instantaneously when the product is heated to 76°C (168.8°F). Note that this study referenced only one serotype of *Salmonella* in a single matrix. If a facility were to choose to use a thermal processing step as a preventive control for pathogens, data like this could be utilized as validation that certain time and temperature combinations will destroy an undesirable microorganism. Importantly, the facility would also need to consider any unique aspects of their animal food or manufacturing that could impact the time and temperature needed to adequately destroy any pathogens that may be present.

There is not strenuous data for all undesirable microorganisms in all animal food matrices. Scientific data, including human food research, can be used as helpful reference points. However, the time × temperature combinations may need to be validated in specific matrices and/or processing systems.

The information referenced in this slide include:

- American Feed Industry Association (AFIA). 2010. ***Salmonella* Control Guidelines.** <http://www.afia.org/resources.asp>
- Institute of Food Technologists (IFT). 2000. **Kinetics of Microbial Inactivation for Alternative Food Processing Technologies.** <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm100158.htm>

Validation Example

- Data sources for extrusion temperature
 - IFT Report to FDA, 2000 & AFIA *Salmonella* Control Guidelines, 2011
 - 170.6°F (77°C) of moist heat (22% moisture) for 1 second adequate for *Salmonella* destruction of 10⁶ log initial population
 - Published study (Bianchini et al., 2012)
 - Greatest reduction (~10⁵) of *E. faecium* occurs at 178°F (81.1°C) and 28.1% moisture
 - Firm's internal validation using their matrix, equipment
 - Minimum actual temperature 175.6°F
 - Use these sources to make determination.
 - **Set minimum parameter value at 178°F**
 - **Set minimum operating limit at 180°F**



When specific examples, such as scientific literature and internal testing, are used for validation of a preventive control, copies of the literature or supporting records from internal testing must be maintained by the facility. The information could be included in the Food Safety Plan or alternately a reference to location of the documentation could be included in the Food Safety Plan.

In addition to the two previously-cited references, the Bianchini et al. (2012) literature can be found at:

Bianchini, A., Stratton, J., Weier, S., Hartter, T., Plattner, B., Rokey, G., and Eskridge, A. M. (2012).

Validation of Extrusion as a Killing Step for Enterococcus Faecium in a Balanced Carbohydrate-Protein Meal by Using a Response Surface Design. Journal of Food Protection, 75(9), 1646-1653.

Slide 32

This validation example for control of *Salmonella* relies on three different sources. The first examples are published reports, namely the IFT Report to FDA in 2000 and the AFIA *Salmonella* control guidelines. The second source is a peer-reviewed study published by Bianchini et al. in 2012. The third source is the firm's own internal process data that showed the minimum actual temperature to destroy *Salmonella*, with their specific matrix and equipment was 79.8°C (175.6° F). With this in mind, the firm decides to set a minimum parameter value of 81.1°C (178° F), and an operating limit of 82.2°C (180° F). Setting the operating value above the parameter value is not a requirement, but is a good practice.

Each of these sources could be used as acceptable validation for the process control for the control of *Salmonella*. As previously stated, a facility would need to ensure that the sources are comparable to the animal food and manufacturing processes utilized by that facility. Different animal food matrices and manufacturing environments may alter the specific time or temperature needed to destroy pathogens.


**Slide 33**

The following slides provide an example of how a processing preventive control may be utilized in an animal Food Safety Plan.

Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis		
Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards	
Ingredients	B	<i>Salmonella</i> spp.
	C	Thiamine deficiency
	P	Metal, plastic, bone, glass, wood




FOOD SAFETY PROMOTIVE COMMISSION ALLIANCE
7-34

Slide 34

In the example plan, *Salmonella* has been identified as a known or reasonably foreseeable biological hazard. This hazard could enter the facility along with received ingredients.

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE		mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES		mm/dd/yy

Table 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
<i>Salmonella</i> spp.	I – High	A – High	Yes	FDA <i>Salmonella</i> CPG 690.800




FEDERAL SUPPLY PRACTICE CENTER FOR ANIMALS
7-35

Slide 35

In Chapter 5, the determination of severity and probability was discussed. Because *Salmonella* can potentially cause illness in both animals and humans, and because pet foods are direct human contact foods with a zero tolerance level for the pathogen according to the FDA Compliance Policy Guide, it was determined that the hazard requires a preventive control.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy


Table 1. Hazard Analysis		
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify Known or Reasonably Foreseeable Hazards	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
<i>Salmonella</i> spp.	Extrusion temperature	1


Slide 36

Salmonella is a heat-sensitive pathogen that can be destroyed at particular time and temperature combinations. The extrusion process used to manufacture dry dog and cat foods operates within temperature parameters sufficient to kill *Salmonella*, and is therefore chosen as the preventive control for the hazard. This is the first preventive control identified in the example Food Safety Plan.

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE		mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES		mm/dd/yy

Table 2. Description of Preventive Controls				
Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
Hazard Requiring a Preventive Control	Appropriate Control for Hazard Requiring a Preventive Control	Preventive Controls Number	Preventive Control Category	Parameters (if applicable)
<i>Salmonella</i> spp.	Extrusion temperature	1	Process Control	Extruder barrel temperature $\geq 178^{\circ}\text{F}$ (instantaneous 10^6 reduction)




7-37

Slide 37

Table 2 of the Food Safety Plan describes the preventive controls and any applicable management components, which are shown on the next slide.

In this example, the facility's internal testing confirms that a minimum acceptable temperature to destroy *Salmonella*, given their specific process and matrix, is 178°F . This parameter agrees with external validation sources. Thus, the parameter for the process control is that all animal food must be extruded at temperatures at or exceeding 178°F . As one mechanism to ensure that the animal food is continually extruded above the minimum temperature, the facility chooses to set an operating limit of 180°F .

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food		ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	mm/dd/yy
Table 2. Description of Preventive Controls				
Preventive Control(s)	Management Components			
(1)	(6)			
<i>Hazard Requiring a Preventive Control</i>	Monitoring (if applicable)			
	What	How	Frequency	Who
<i>Salmonella spp.</i>	Automation system	Extruder records, thermometer readings	Continuous with exception alarms	Shift operator running the automation system and/or Qualified Individual



7-38

Slide 38

In order to assure the preventive control is properly implemented, the automation system used to operate the equipment is monitored. This can be done in real-time by viewing temperature readings to monitor that the temperature does not fall below the minimum parameter value of 178°F. Process records will also be reviewed at the end of each shift by the extruder operator in order to verify that the temperature parameter was met for all extruded dog and cat food produced during the shift.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 2. Description of Preventive Controls		
Preventive Control(s)	Management Components	
(1)	(7)	(8)
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records
Salmonella spp.	If animal food is manufactured below the parameter value: 1) root cause will be identified, 2) re-training or equipment re-calibration will occur, 3) affected animal food will be evaluated for safety, 4) affected animal food will be reworked, diverted, or properly disposed of, and 5) the Food Safety Plan will be reanalyzed, when appropriate.	Extruder records, validation documents, corrective action records, training records, thermometer accuracy records, thermometer calibration records, verification records

7-39

Slide 39

Column 7 identifies the corrective actions the facility will utilize if the minimum temperature falls below 178°F. If animal food is manufactured below the parameter value: 1) root cause will be identified, 2) re-training or equipment re-calibration will occur, 3) affected animal food will be evaluated for safety, 4) affected animal food will be reworked, diverted, or properly disposed of, and 5) the Food Safety Plan will be reanalyzed, when appropriate.

Records generated for this process control include process records (such as extruder records), training records, and verification records.

Pet Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds	PAGE X of Y	
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 3. Description of Preventive Control Verification Activities	
Activity	Description of Activity
Type of Validation	<ul style="list-style-type: none"> IFT Report to FDA: Kinetics of Microbial Inactivation, 2000 AFIA <i>Salmonella</i> Control Guidelines, 2010 Bianchini et al. in 2012. Internal process data: minimum required temperature = 175.6 F
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	Daily checks to confirm thermometer accuracy Quarterly calibration of thermometers Test and hold procedures per SOP 506.3
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

Slide 40

Verification activities include record review, establishing appropriate validation, and reanalysis.

In this example, all monitoring and corrective action records are reviewed within seven working days by (or under the oversight of) the PCQI. If the review time-frame must exceed seven working days, a written justification is provided by the PCQI.

Validation for the process control is listed, and corresponds to the resources described earlier in this chapter.

Thermometers will be checked for accuracy daily and will be calibrated quarterly. Because process records are reviewed at the end of a shift, test-and-hold procedures are used to assure all products shipped have met the established parameters for the process control.

A reanalysis of the plan is conducted every three years, as necessary when changes occur, or when it is determined that a preventive control is ineffective.

Process Preventive Controls Summary

- Process controls are based on the control of parameters and established limits.
- For each process control identified, the following must be documented:
 - Parameters that must be met
 - Monitoring procedures, including what, how, frequency and who
 - Corrective actions that identify the implicated product, determine its disposition, correct the cause and determine that the preventive controls are working again
 - Verification and records



Slide 41

Process controls focus on processing steps where control can be applied to significantly minimize or prevent hazards requiring a preventive control. Maximum and/or minimum parameter values must be established to effectively control a food safety hazard. Monitoring procedures are required to ensure that the process control effectively addresses the hazard. Such procedures must specify what will be monitored, how it will take place, how often it will be done, who will do it, and what monitoring records will be generated. Corrective actions must be in place that describe what to do when parameters are not met and the process is considered to be ineffective in controlling the hazard. Finally, verification must be conducted to ensure that management components are appropriately used, that the process control is being properly implemented, and that the hazard is effectively controlled.

NOTES

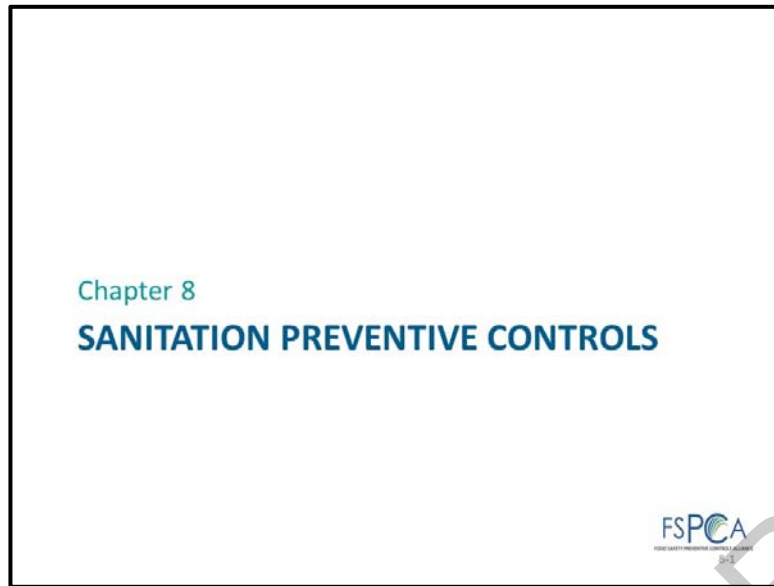
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

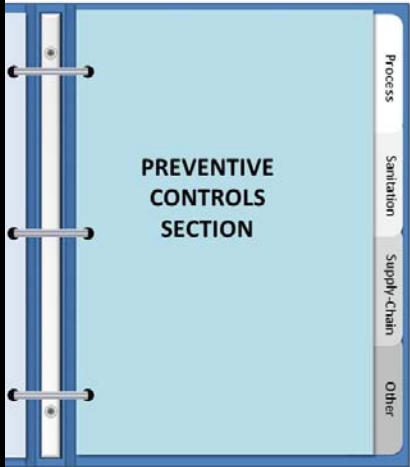
CHAPTER 8. Sanitation Preventive Controls



Slide 1

The next preventive control category to be discussed during this course is the sanitation controls.

Sanitation Preventive Controls Objectives



In this module, you will learn:

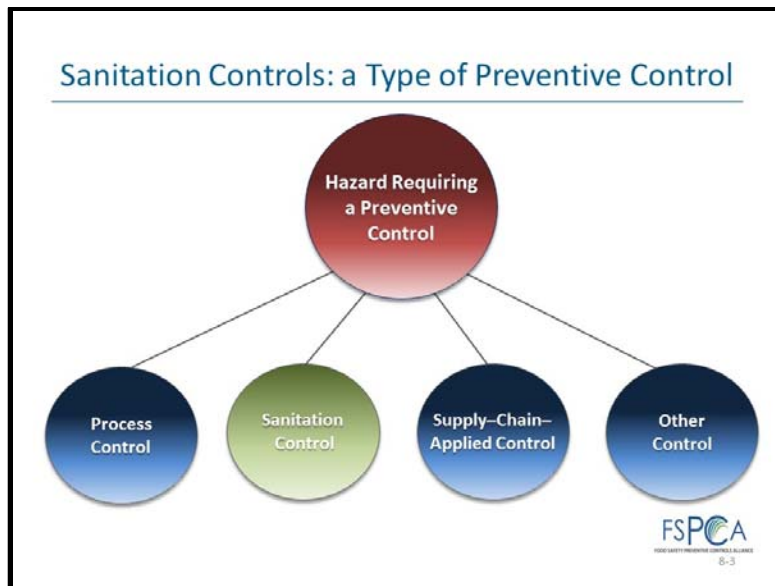
- The difference between sanitation CGMPs and sanitation controls
- The purpose and importance of sanitation preventive controls
- Required management components for sanitation preventive controls

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ACT

8-2

Slide 2

The goals for this module are to describe 1) the difference between sanitation CGMPs and sanitation controls, 2) the purpose and importance of sanitation controls, and 3) the required management components for sanitation controls.

**Slide 3**

Chapter 7 described how preventive controls could be used to address hazards associated with a process step. The sanitation controls describe a more holistic approach, and are typically used to prevent cross-contamination of pathogens after a process control.

21 CFR 507.34(c)(2) – Sanitation Controls

- (c)(2) Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:
 - (i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and
 - (ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

8-4

Note that *environmental pathogen* is defined in 21 CFR 507.3 as, “a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic spore-forming bacteria.”

Slide 4

This slide is a continuation of the preventive controls section that we introduced in Chapter 7 during our discussions of process controls. The regulations for sanitation controls are listed in Part 507.34(c)(2), which can be found on the top of page 56346 in Appendix 1. In this curriculum, the term “sanitation preventive control” is used interchangeably with “sanitation control” and both terms have the meaning specified in 21 CFR 507.34(c)(2).

The regulation requires activities to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling.

Sanitation controls must include, as appropriate:

- Cleanliness of animal food-contact surfaces, including utensils and equipment
- Prevention of cross-contamination from objects, personnel, and raw product

Sanitation Controls: a Type of Preventive Control

- Sanitation controls are used to control hazards that have met the threshold of being a *hazard requiring a preventive control*.
- Specifically, sanitation controls are most appropriate to control:
 - Environmental pathogens when finished product is exposed to the environment prior to packaging
 - Pathogens transferred through cross-contamination



Slide 5

Sanitation controls are used to control biological hazards that have been identified as a *hazard requiring a preventive control*. Like all other hazards that meet this definition, the combination of severity and probability warrant the hazard's evaluation as requiring a sanitation control. The use of a sanitation control, in the sense of a preventive control, is different than the use of sanitation CGMPs.

Not all facilities will have sanitation controls. They are most appropriate to control environmental pathogens when finished product is exposed to the environment prior to packaging and to control pathogens transferred through cross-contamination. Because the primary undesirable microorganisms in animal food are *Salmonella* spp. and *Listeria monocytogenes*, most of this chapter will describe efforts to control those pathogens. If a facility does not have a biological hazard that requires a preventive control, it is unlikely a sanitation control would be required.

Sanitation Controls are Different than CGMPs

- Prerequisite programs, such as CGMPs, address some parts of sanitation.
 - 21 CFR 507.14 Personnel – Employee hygiene practices
 - 21 CFR 507.17 Plant and Grounds – Facility design/layout
 - 21 CFR 507.19 Sanitation – Utensil/equipment surfaces
 - 21 CFR 507.25 Plant Operations – Plant cleanliness
 - 21 CFR 507.27 Holding and Distribution – Animal food storage



Slide 6

Sanitation controls are different than the CGMPs that address sanitation, but the two work together to establish a sound foundation for the animal food safety system. The considerations on the slide above are potential examples where CGMPs address sanitation and work to prevent cross-contamination. For instance, it is important for employees to understand that their actions can contribute to product contamination. Employees working in a raw product area subject to biological hazards should not work with a finished product without washing and sanitizing their hands, equipment, or utensils to avoid cross-contamination. Personal cleanliness is also important to prevent product contamination and is generally managed through CGMPs. Workers must wear clean and appropriate attire. For example, an employee who spills a potential chemical hazard, such as petroleum-based grease, on his or her clothing should take appropriate hygiene practices to prevent subsequent contamination to animal food.

Plant design must prevent potential contamination of animal food, animal food-contact surfaces, and animal food packaging material by separating operations where contamination is likely to occur. This means separating raw product and unpackaged finished product subject to biological hazards to avoid contamination.

Goals of Sanitation Controls

- Cleanliness of animal-food contact surfaces
- Prevention of cross-contamination
 - From insanitary objects and personnel
 - From raw product to processed product



An animal food contact surface is the area of equipment or utensils that comes into contact with animal food. For example, the inside of a conveyor or mixer is an animal food contact surface, while the outside of that equipment is not. In addition, the blade of a shovel used to move an ingredient is an animal food contact surface, while the handle is not.

Slide 7

Lack of effective sanitation controls have contributed to major recalls of animal food. When a hazard analysis identifies a hazard requiring a sanitation control, the procedures, practices, and processes used to manage these hazards must be developed and documented. As appropriate to the animal food, facility and the preventive control's role in the animal food safety system, sanitation controls may involve procedures to ensure the cleanliness of animal food-contact surfaces, including those of utensils and equipment. Sanitation controls may also involve procedures to significantly minimize or prevent microbial cross-contamination.

Preventing hazard transfer from insanitary objects (such as dirty equipment and environmental sources) and from personnel to animal food, to animal food packaging material, and to other animal food contact surfaces may be appropriate depending on the operation. Preventing transfer from raw material to finished product may also be appropriate in some situations (e.g., from raw material to finished product subject to biological hazard contamination).

Personnel can play a big role in preventing transfer of contamination. Animal food safety and animal food hygiene training is required by the *Preventive Controls for Animal Food* rule. This can help employees to understand the important role they play in the animal food safety program.

Examples of Sanitation Controls

- Sanitizing animal food-contact surfaces
- Personnel practices/hygienic zoning



Other sanitation controls, such as dry or wet cleaning, may exist. The type of sanitation control depends upon the facility.

There is additional discussion in the Preamble of the *Preventive Controls for Animal Food* rule regarding the role of wet cleaning. In many cases, dry cleaning is allowable and sufficient. In cases when wet cleaning is necessary, the water must not be a subsequent source of contamination of animal food.

Slide 8

The types of appropriate sanitation controls depend upon the facility. Examples of potential sanitation controls include the sanitizing of animal food-contact surfaces and control of personnel practices, such as hygienic zoning. Before we can discuss these examples further, it is appropriate to visit the regulatory definition for *sanitize*.

21 CFR 507.3 – Definitions: Sanitize

- *Means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.*

8-9

Note that 'sanitize,' as defined here, is different than the more generic term, 'sanitation.' The Preamble of the *Preventive Controls for Animal Food* rule describes this difference. Sanitation describes general cleaning practices, which are primarily encompassed in the CGMPs. Meanwhile, 'sanitize' or 'sanitizing' means the treating of cleaned surfaces as described in the definition. When used in this sense, these sanitizing activities are typically used as sanitation controls.

Slide 9

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

Examples of Sanitation Controls: Sanitizing Surfaces

- Appropriate when the destruction of microorganisms is required
 - Systems, such as steam systems, that both clean and sanitize surfaces meet the requirement for sanitizing
- Generally more aggressive than routine sanitation procedures if an environmental pathogen has become established
- Surface sanitizing procedures must describe purpose, frequency, who, steps, and how to manage the preventive control (monitoring, corrections, verification, records).



Slide 10

One of the examples of a sanitation control is the sanitizing of animal food surfaces – and this is Preventive Control #2 for ABC Pet Food Manufacturing Facility. Preventive Control #2 from this Food Safety Plan is used as an example in the remainder of this chapter.

Sanitizing animal food contact surfaces is most appropriate when the destruction of microorganisms is required. Some facilities utilize steam systems for sanitizing, which clean and sanitize the surface in a single step. This meets the requirements of sanitizing. Notably, sanitation controls are typically more aggressive than routine sanitation procedures if an environmental pathogen has become established. For example, *L. monocytogenes* is exceedingly difficult to remove from a manufacturing facility once it is persisting. As such, more strenuous sanitizing may be appropriate to significantly minimize the hazard.

Regardless of the sanitizing manner, explicit details should be documented in the Food Safety Plan when developing surface sanitizing procedures. These details include the purpose of the surface sanitizing activity, frequency, who is responsible for the activity, steps to carry out the sanitizing activity, and how the preventive control will be managed through monitoring, appropriate corrections, or corrective actions (if necessary), verification of the preventive control activities, and appropriate records.

While sanitizing animal food contact surfaces may be used in some food facilities, it is not appropriate for all animal food manufacturing facilities to sanitize surfaces. In fact, it is impractical or impossible in many facilities to sanitize the animal food-contact surfaces. However, sanitizing animal food contact surfaces is relevant when the hazard analysis process identifies that a *hazard requiring a preventive control* is to be controlled by a sanitation control.

Hazard Analysis	PRODUCT: Dry extruded dog and cat food	PAGE X of Y	Pet Food Example	
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE		mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES		mm/dd/yy

SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.

Frequency: Before operations begin and at the end of daily production

Who: Sanitation team member

Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet

Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.

Corrective Action: Identify and correct root cause; re-train employees or re-calibrate equipment; evaluate all affected animal food for safety; prevent affected animal food from entering commerce by reworking, diverting, or properly disposing of; reanalyze the Food Safety Plan when appropriate

Records: Daily Sanitation Sheet

Verification: Supervisor (daily) and PCQI (within 7 working days) reviews Daily Sanitation Sheet

In part, the definition of sanitize means to treat clean surfaces to kill microorganisms. In order for sanitizers to work effectively, the surface must first be cleaned. That cleaning process is listed as part of the sanitizing procedure in this example.

While the example uses a quaternary ammonium sanitizer, other registered sanitizing chemicals, dry products, recognized hot water, or steam sanitizing procedures may be used.

Slide 11

Preventive Control #2 requires sanitizing of animal food contact surfaces. The sanitizing procedure for finished product (post-extrusion) animal food contact surfaces in the ABC Pet Food Manufacturing Facility appears above. This is an example of how a sanitation control may be applied. The format used can vary considerably.

The purpose of this procedure is to clean and sanitize finished product animal food contact surfaces (equipment and utensils), because it is important for reducing cross-contamination or recontamination with environmental pathogens that may impact animal food safety.

The procedure is to occur prior to operations beginning and at the end of daily production by a sanitation team member.

In the procedure, the first step will be clean post-extrusion surfaces by removing gross material, wiping the surfaces clean with an appropriate cleaning solution, and rinsing with clean water. Following the cleaning, a sanitizing solution (200 ppm quaternary ammonium compound solution) is sprayed on surface, which is then dried.

The SOP shows the monitoring, correction, corrective action, documentation, and verification activities that are expected to accompany this sanitation control. This facility has identified that the supervisor must complete daily verification that the preventive control is completed. However, the PCQI reviews those records on a weekly basis. The daily review is an optional activity being conducted by the facility to verify monitoring is being conducted according to the facility's procedures. This verification could instead be done by or under the direction of the PCQI through his/her record review, as is required to be done within 7 working days of the monitoring activity.



Slide 12

Sanitizing animal food contact surfaces is not the only control useful in preventing contamination of animal foods. Another potential type of sanitation control is hygienic zoning. The concept of hygienic zoning was developed for facilities where both raw materials potentially contaminated with undesirable microorganisms and finished products are handled. Every facility has different needs, depending on the product, the structure, traffic patterns and other factors involved with processing and handling animal food.

The slide above discusses different types of hygiene areas. Non-manufacturing areas do not require the same level of sanitation as animal food processing areas. Transition areas into a processing space or those in post-pathogen controls areas should be equipped with materials to minimize the potential for transferring potential pathogens into the facility. For example, hand-washing and footbath areas are typically available in transition areas. More attention to sanitizing and primary pathogen control is needed in areas that handle finished product that are exposed to the environment.

Control of traffic patterns between these areas with different levels of hygiene can minimize the transfer of hazards. Techniques that may be useful include:

- Dedicated equipment in different areas, especially when it is difficult to clean (e.g., carts, forklifts)
- Use of color-coded uniforms or bump caps for people who work on the raw material side and those who work on the finished product side
- Linear flow through a facility, such that raw material does not enter the finished product area.

It is understood that the above may not be practical in all situations. However, there is a requirement that efforts are made to prevent cross-contamination when *hazards requiring a preventive control* are identified through hazard analysis. Preventive controls can address this through zoning and other means, as dictated by the situation at the facility.

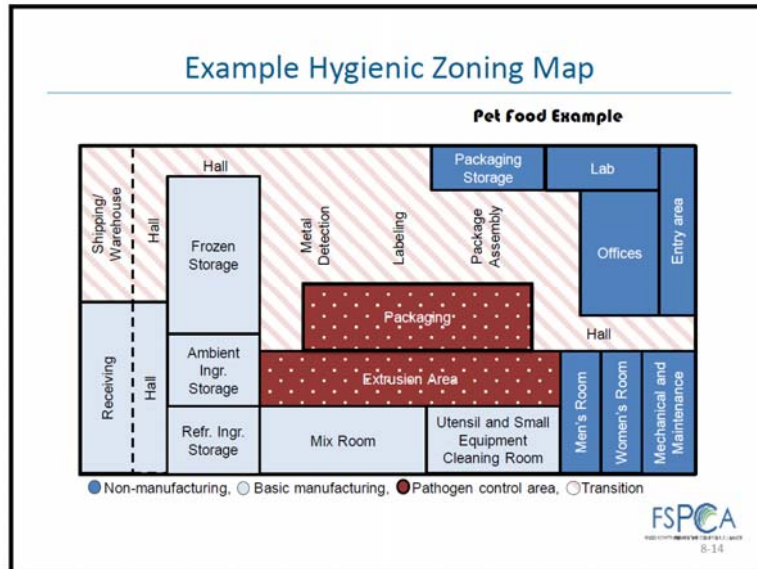
Hygienic Zoning Considerations

- Infrastructure
- Personnel, materials and other traffic flow
- Cross-over areas
- Room air
- Compressed air, if used in direct product contact
- Adjacent and support areas



Slide 13

Each facility must determine the need for and scope of a sanitation control based on the potential for product contamination. The assessment should take into account the physical structure of the facility; personnel, packaging, and ingredient traffic flows; and any cross-over areas. The assessment should also consider potential contaminants from raw materials, air flow, support areas and activities taking place in the facility, which may include potential microbiological concerns. The sanitation controls must address targeted environmental pathogens if relevant to the product being produced.

**Slide 14**

The map above is a hygienic zoning example for ABC Pet Food Manufacturing Facility. There are four main areas of this map: 1) non-manufacturing, 2) basic manufacturing, 3) pathogen control, and 4) transition areas.

- 1) The non-manufacturing areas, depicted in dark blue shaded boxes, are areas where manufacturing does not occur, such as personnel entrances, laboratories, packaging storage, offices, maintenance and mechanical rooms, and restrooms.
- 2) The basic manufacturing areas, depicted in light blue shaded boxes, are areas where manufacturing occurs prior to the process control step (extrusion). These areas include material receiving, hallways, ingredient storage, mixing, and utensil cleaning rooms. The presence of undesirable microorganisms may occur in these areas because of their exposure to contaminated raw material. This is acceptable because the facility has a process control for the hazard, but these areas should be maintained so as to not grow or proliferate the undesirable microorganism.
- 3) The pathogen-control area, depicted in the red box with white polka dots, is the highest risk location for cross-contamination. This is where finished, extruded, pathogen-free product is exposed to the environment prior to packaging. This is the most tightly controlled area to limit the potential for cross-contamination.
- 4) Areas after packaging are transition areas, depicted in the striped areas, include hallways, packaging assembly, labeling, metal detection, and shipping/warehouse. While finished product is not exposed in these locations, it is important to maintain a pathogen-free environment.

Employee zoning takes into account these zones and develops protocols for restricting employee movement from one zone to another, or describes requirements for what must occur prior to entry if these zones must be crossed. For example, employees in the packaging area should have limited contact with those receiving raw materials. There should be clear procedures for employees that cross over multiple areas, such as maintenance staff. If a member of maintenance works in a refrigerated storage area, returns to his workbench in the maintenance shop, and then must enter the packaging area, procedures should be established to ensure the employee does not contaminate his shop or the packaging area with undesirable microorganisms.

Management Components Appropriate for Ensuring the Effectiveness of Different Controls

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

Sanitation controls do not require validation because the control either cannot be validated, in the case of visual inspection, or is typically conducted by someone else, such as the sanitizer manufacturer to ensure its effectiveness. It is appropriate to ensure that the correct sanitizer is selected for the type of surface, animal food, and pathogen being targeted.

Slide 15

The management components required for sanitation controls include monitoring, corrective actions and corrections, and verification activities. Note that validation is not a requirement for sanitation controls. These management components will be discussed next.

Monitoring of Sanitation Controls

- Monitoring the critical elements of the sanitation process and procedures
- Monitoring the implementation of other relevant controls, such as hygienic zoning



Slide 16

Sanitation controls must be monitored and results recorded as appropriate. As discussed above, sanitizing procedures used as a preventive control require monitoring records. An example of the type of record that could be used for monitoring the surface sanitizing activity is illustrated next.

Pet Food Example				
Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y	
PLANT NAME	ABC Pet Food Manufacturer		ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	mm/dd/yy
DATE: <u>4/18/2016</u> Daily Sanitation Sheet				
Procedure	Prior to Operations (5:47 AM)	End (6:36 PM)	Comments or Corrections	Initials
Cleaning Animal Food-Contact Surfaces				
• Surface of equipment or utensil cleaned w/ squeegee	✓	✓	n/a	CS
• Surface wiped with clean cloth dipped in detergent	✓	✓	n/a	CS
Detergent type and strength: <u>ABC Cleaning Solution, 2 oz. per gallon water</u>				
• Surface rinsed with clean water	✓	✓	n/a	CS
Sanitizing of Animal Food-Contact Surfaces				
• Entire surface sprayed with sanitizer	✓	✓	n/a	CS
Sanitizer type and strength: <u>Quaternary ammonia compound, 200 ppm</u>				
• Allow at least 1 minute contact time of sanitizer	✓	✓	n/a	CS
• Allow surface to air dry (apx. 5 minutes)	✓	✓	n/a	CS
• ***Inspected for residual material and cleanliness	✓	✓	n/a	CS
• ***Sanitizer concentration measured: <u>200 ppm</u>	✓	✓	n/a	CS
Supervisor signature: <u>Sarah Supervisor</u>		Date: <u>4/18/2016</u>		
PCQI signature: <u>Frank T. Gaudin</u>		Date: <u>4/22/2016</u>		

This facility chose to use a two-step verification method. First, the supervisor reviews the monitoring record daily. Second, the PCQI reviews the record within 7 working days of the activity occurring. Verification of monitoring is required and the PCQI's review of the records could satisfy the requirement.

Slide 17

An example of a Daily Sanitation Sheet for dry extruded dog and cat food is illustrated above. The example is from our ABC Pet Food Manufacturing Facility. This form serves as documentation of the monitoring and verification steps for Preventive Control #2 according to the facility's SOP for finished product animal food contact surface sanitizing (see slide 8-11).

The concentration of the cleaning solution was recorded (ABC Cleaning Solution, 2 oz. per gallon water). The sanitizer concentration is tested using a sanitizer strip, and the concentration is recorded (quaternary ammonia compound, 200 ppm). The frequency of testing is recorded (prior to start and at the end of operations), as well. In this example, the monitoring activities are the inspection for residual material and cleanliness and the measurement of the sanitizer concentration. The type of monitoring activity and its frequency can change depending upon the facility, but both must occur. A chemical supplier can help provide guidelines for monitoring methods and frequency in many situations.

In addition to the sanitizer concentration and frequency, other key parts of this form include the date, time, and initials of the individual performing the monitoring task. These must be included on a monitoring record and must be recorded each time they perform the task.

The last component of this form is the designated space for verification. In the facility's SOP for sanitizing post-extruder animal food contact surfaces (see slide 11), the supervisor is required to review and sign the Daily Sanitation Sheet, and the PCQI must verify it within 7-working days. Space is provided for their signatures and dates of those signatures.

Corrections and Corrective Actions for Sanitation Controls

- Depends on situation and could include:
 - Re-clean affected areas
 - Re-sanitize contact surfaces and/or utensils
 - Re-train qualified individual(s)



Slide 18

When deficiencies of a sanitation preventive control are encountered, corrective actions or corrections must be made in a timely manner. The nature of the action depends on the specific situation. In some situations, corrections may be more appropriate than corrective actions. Sometimes corrections are relatively easy and can be done when animal food safety is not impacted. For example, if the sanitizer concentration from the previous example is determined to be incorrect, a new sanitizer solution should be prepared and the equipment should be re-sanitized. Note that re-sanitizing equipment can be avoided if the sanitizer concentration is checked before it is used. The facility may also determine that personnel cleaning the equipment may need to be re-trained to ensure proper preparation of sanitizer solutions in the future.

21 CFR 507.3 – Definitions: Correction

- *An action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).*



Slide 19

Note that the discussion in the previous slide focused on a correction, not a corrective action. The term correction is defined by the *Preventive Controls for Animal Food* rule as an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

Hazard Analysis	PRODUCT: Dry extruded dog and cat food	PAGE X of Y	Pet Food Example	
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE		mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES		mm/dd/yy

SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.

Frequency: Before operations begin and at the end of daily production

Who: Sanitation team member

Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet

Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.

Corrective Action: Identify and correct root cause; re-train employees or re-calibrate equipment; evaluate all affected animal food for safety; prevent affected animal food from entering commerce by reworking, diverting, or properly disposing of; reanalyze the Food Safety Plan when appropriate

Records: Daily Sanitation Sheet

Verification: Supervisor (daily) and PCOI (within 7 working days) reviews Daily Sanitation Sheet

Slide 20

The example above from the ABC Pet Food Manufacturing illustrates how corrections can be described in a sanitizing procedure. This correction procedure informs operators the action that must be taken if procedures are not properly followed. Because these are correction procedures and not corrective action procedures, completion of a corrective action report is not required.

Type	Correction	Corrective Action
When is it needed?	When a minor and isolated problem is identified in a timely manner and does not impact product safety	When preventive controls are not properly implemented
What does it require?	<ul style="list-style-type: none"> Identify and correct the problem 	<ul style="list-style-type: none"> Identify and correct the problem Reduce the likelihood that the problem will recur Evaluate all affected animal food for safety Prevent affected animal food from entering commerce as necessary Reanalyze the Food Safety Plan when appropriate
Example	An animal food contact surface was not properly cleaned and sanitized; re-cleaning and re-sanitizing is necessary prior to re-starting production.	Finished product was manufactured below the parameter value; reworking is necessary prior to packaging.

FSPCA
8-21

Typically, corrective actions are necessary for process controls. Corrections are more likely to occur in sanitation controls. However, if repeated corrections are necessary, corrective action may be appropriate.

Slide 21

Actions to correct conditions or practices related to cleanliness and prevention of cross-contamination must be taken in a timely manner. When timely action is taken, “corrections” such as those described in the sanitizing procedure, may be adequate. If action is not taken in a timely manner (e.g., unsanitary conditions exist for an extended period and result in product cross-contamination), a full corrective action may be required.

The slide describes the differences between corrective action and correction. A corrective action is needed when preventive controls are not properly implemented. When that occurs, the facility must identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, prevent affected animal food from entering commerce as necessary, and reanalyze the Food Safety Plan when appropriate. An example of a situation that would require a corrective action is if finished product was extruded at a temperature below the set parameter value. In that case, reworking the product would be necessary prior to packaging. This would impact product safety, so a process control would be needed as the corrective action.

Comparatively, a correction is when a minor and isolated problem is identified in a timely manner and that problem does not impact product safety. In this case, no additional steps are required beyond identifying and correcting the problem. An example of a correction is if residue is found on an animal food contact surface prior to production, which would require re-cleaning and re-sanitizing.

All corrective actions (and, when appropriate corrections) must be documented and are subject to verification to make sure that appropriate decisions were made and record review.

Verification of Sanitation Controls

- Activities that demonstrate that sanitation controls are operating as intended
- Methods may vary
- Potential examples
 - Review of sanitizing records
 - Environmental monitoring for environmental pathogens



Some facilities may monitor the hazard they are trying to control directly. However, there may be constraints for directly measuring some undesirable microorganisms, such as potential variability, cost, or speed with which they can be analyzed. For this reason, facilities may choose to use indicator organisms, which behave similarly to the hazard, but nonpathogenic and more appropriate to monitor.

Examples of indicators include *Listeria spp.*, *Enterobacteriaceae* or ATP swabs. *Listeria spp.* may be an appropriate indicator organism for *L. monocytogenes*. Data is available that supports using *Enterobacteriaceae* as an indicator organism in environmental monitoring. Swabbing for ATP indicates cleanliness of surfaces.

Slide 22

Verification activities that may be appropriate for sanitation controls include confirming that the procedures, such as hygienic zoning or surface sanitization, are working as intended. The methods used to verify these activities vary based on the type of sanitation control, facility, and animal food manufactured processed, packed, or held.

Verification activities may include reviewing records, such as Daily Sanitation Sheets. However, they may also include environmental monitoring of undesirable microorganisms or indicator organisms to ensure hazards are properly controlled.

Environmental Monitoring for Sanitation Controls

- Applicable “...for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control...”
§ 507.49(a)(3)
- May be required to verify the effectiveness of sanitation controls for certain facilities
 - E.g., facilities where finished product is exposed to the environment
- Must be tailored to each facility
- A useful program diligently *tries to find* the organism!

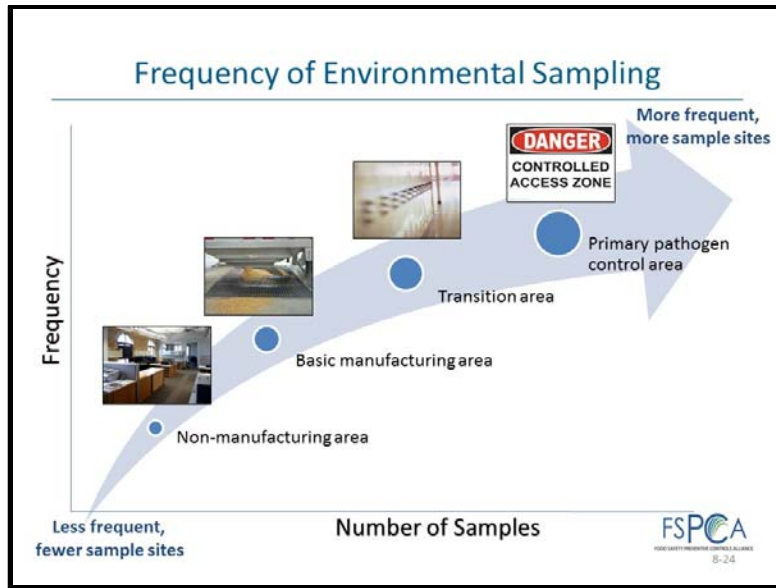


Environmental monitoring is specifically described as being appropriate for *Salmonella* spp. and *Listeria monocytogenes* (21 CFR 507.3).

Slide 23

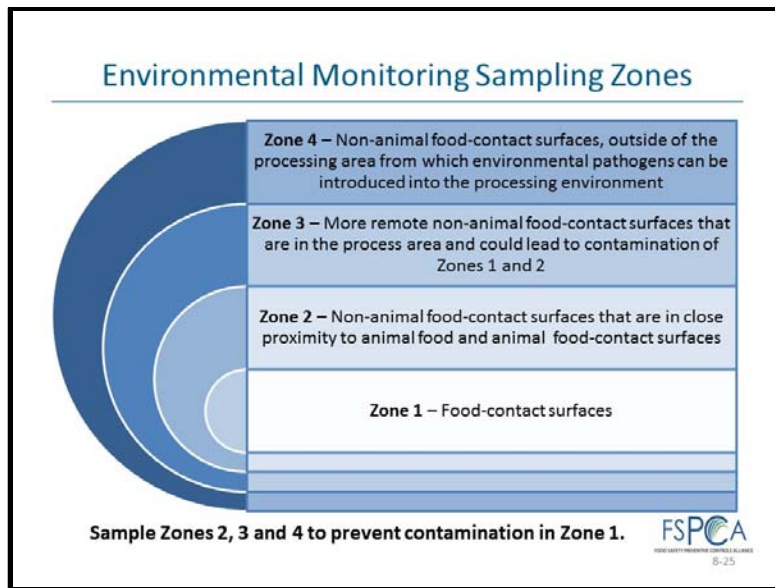
Environmental monitoring is usually applicable for a pathogen or an appropriate indicator organism when an environmental pathogen is a *hazard requiring a preventive control*. In this case, environmental monitoring helps verify the effectiveness of sanitation controls for certain facilities. For example, this would be common in facilities where finished product subject to biological hazards is exposed to the environment before packaging.

An effective environmental monitoring program diligently tries to find the pathogen or indicator organism of concern so that corrections can be made *before* product is compromised. Environmental monitoring is a verification procedure for such a facility. Corrective actions procedures (instead of corrections) must document actions to be taken when the environmental pathogen or an indicator organism is detected.

**Slide 24**

There are two major considerations when determining procedures for environmental monitoring. First, one must consider where in the facility layout to focus swabbing activities. Second, one must consider which surfaces to swab within each of those areas.

Since the objective of environmental monitoring is to detect potential sources of contamination, sampling typically focuses on the areas of greatest concern. There are less frequent and fewer sample sites in non-manufacturing areas, such as office areas. The frequency and number of sampling sites increases based on risk area, where the most frequent and largest number of sampling sites are in the primary pathogen control area, such as in the packaging area described previously where finished product is exposed to the environment.



Slide 25

Once the frequency and number of sampling sites is determined within each processing area, the specific sampling sites within each area are typically determined based on zones. Zoning helps prioritize the locations and appropriate frequency of swabbing for environmental monitoring.

Zone 1 represents animal food contact surfaces, such as the interior of bins, conveyors, utensils, and equipment that come into direct contact with the animal food.

Zone 2 includes areas adjacent to animal food contact surfaces, which are sometimes referred to as indirect product contact surfaces. Examples include bearings and the exterior of equipment panels.

Zone 3 includes other surfaces within the area, such as floors, walls, ceilings, and drains.

Zone 4 encompasses all other non-production areas of a facility, such as hallways, maintenance shops, and restrooms.

Sampling of Zone 1 is often difficult because it is covered during the process. Thus, sampling Zone 1 is infrequent; but when it is done, product should be held until results are found negative to prevent a potential recall. Instead, most facilities focus on sampling Zones 2 and 3 in order to detect potential contamination *before* it is found in product so it can be corrected.

Environmental Monitoring – People and Tools

- Requires training in technique
 - Identify likely sampling spots
- Tools vary by facility and product type
 - Swabs, sponges, gauze and other options
 - Contact plates
 - Floor sweeps
 - Dust accumulation
 - Air samplers
- Environmental monitoring courses are available for different product categories



Slide 26

Personnel must be trained to conduct environmental sampling and must have a sense for when to deviate from the plan based on observations or special events. The correct tools allow for thorough sampling of various locations, such as cracks, crevices, air, large floor areas, and drains. Because there are a number of variables to consider in order to conduct accurate and effective environmental monitoring, additional training may be appropriate.


**Slide 27**

The following slides provide an example of how a sanitation control may be utilized in a Food Safety Plan. We will return to the Example Food Safety Plan for Dry Extruded Dog and Cat Food that was introduced in Chapter 5, and also discussed in Chapter 7.

Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy


Table 1. Hazard Analysis		
Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards	
Ingredients	B	<i>Salmonella</i> spp.


Slide 28

In the example plan, *Salmonella* has been identified as a known or reasonably foreseeable biological hazard. Ingredients were identified as its potential vector of entry.

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy	
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy	

Table 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
<i>Salmonella</i> spp.	I – High	A – High	Yes	FDA <i>Salmonella</i> CPG 690.800




FEDERAL SUPPLY PRACTICE CENTER FOR ANIMALS
8-29

Slide 29

In Chapter 5, the determination of severity and probability was discussed. Because *Salmonella* can potentially cause illness in both animals and humans, and because pet foods are direct human contact foods with a zero-tolerance level for the pathogen according to the FDA Compliance Policy Guide, it was determined that the hazard requires a preventive control.

Pet Food Example		
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food	PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES mm/dd/yy

Table 1. Hazard Analysis		
Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify Known or Reasonably Foreseeable Hazards	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
<i>Salmonella</i> spp.	Sanitation Control - Post-extruder surface sanitizing	2




Slide 30

Chapter 7 described how extrusion temperature could be used as a process control to reduce *Salmonella*. However, extrusion is a point-in-time mitigation step and does not prevent potential cross-contamination with the hazard after thermal processing. Thus, sanitizing post-extruder animal food contact surfaces was determined necessary to prevent cross-contamination. This is Preventive Control Number 2 in the Example Food Safety Plan for Dry Extruded Dog and Cat Food (Preventive Control Number 1 was extrusion temperature).

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE		mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES		mm/dd/yy

Table 2. Description of Preventive Controls				
Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
Hazard Requiring a Preventive Control	Appropriate Control for Hazard Requiring a Preventive Control	Preventive Controls Number	Preventive Control Category	Parameters (if applicable)
Salmonella spp.	Post-extruder surface sanitizing	2	Sanitation Control	Any residual material on post-extruder surfaces and 200 ppm sanitizer concentration




8-31

Slide 31

Table 2 of the Food Safety Plan describes the preventive controls and any applicable management components. As established by the previous procedure, there are two parameters: 1) any residual material on post-extrusion animal food contact surfaces; and 2) 200 ppm concentration of the quaternary ammonium compound solution.

Pet Food Example				
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food			PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy	
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy	

Table 2. Description of Preventive Controls				
Preventive Control(s)	Management Components			
(1)	(6)			
Hazard Requiring a Preventive Control	Monitoring (if applicable)			
	What	How	Frequency	Who
Salmonella spp.	Visual inspection of surfaces, sanitizer concentration	SOP 201.2	Before operations begin and end of daily production	Sanitation team member


Slide 32

The monitoring for this preventive control is visual inspection of the animal food contact surfaces for gross contamination and using a test strip to test the quaternary ammonium compound solution before its application to clean animal food contact surfaces. The procedures for how to conduct this monitoring are discussed in a company standard operating procedure – SOP 201.2. The monitoring will occur before operations begin and at the end of daily production by a sanitation team member.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy
Table 2. Description of Preventive Controls			
Preventive Control(s)	Management Components		
(1)	(7)	(8)	
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records	
Salmonella spp.	<u>Correction:</u> If residual material is observed on the animal food-contact surface, re-clean and re-sanitize. If sanitizer is not at the proper concentration, make a new solution. <u>Corrective action:</u> 1) root cause will be identified, 2) re-training or equipment re-calibration will occur, 3) affected animal food will be evaluated for safety, 4) affected animal food will be reworked, diverted, or properly disposed of, and 5) the Food Safety Plan will be reanalyzed, when appropriate.	Daily Sanitation Sheet, corrective action and correction records, training records, environmental monitoring records	

Slide 33


If there is residual material on the animal food-contact surface, the surface is to be re-cleaned and sanitized as part of a correction. If the quaternary ammonium solution is not at the proper concentration, a new solution will be made. Both those instances are corrections.

If unsanitary conditions exist for an extended period and result in product cross-contamination or repeated corrections are necessary, corrective action is necessary, where the problem must be identified and corrected, and product must be reworked prior to packaging.

The records required for these activities include the Daily Sanitation Sheet, corrective action and correction records, training records, and environmental swabbing records.

Pet Food Example			
Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 3. Description of Preventive Control Verification Activities	
Activity	Description of Activity
Type of Validation	n/a
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	Environmental monitoring per SOP 213.6 Product testing when necessary per SOP 213.7
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.



FOOD SAFETY PRACTICES FOR PET FOOD MANUFACTURERS
8-34

Slide 34

Verification activities include record review, environmental monitoring, and reanalysis.

The daily sanitation sheet will be reviewed within 7 working days of the documented action unless justified by the PCQI. Environmental monitoring will be conducted according to internal procedures outlined by SOP 213.6, while product testing will be conducted according to procedures in SOP 213.7. Other monitoring records, as well as corrective action and correction records will be reviewed within seven working days. If the review timeframe must exceed seven working days, a written justification is provided by the PCQI.

There is no validation required for a sanitation control.

A reanalysis of the plan is conducted every three years, as necessary when changes occur, or when it is determined that a preventive control is ineffective.

Sanitation Preventive Controls Summary

- Type of preventive controls that differ from Sanitation CGMPs
- Maintain clean animal food-contact surfaces and prevent cross-contamination
- Require monitoring, corrective actions and corrections, and verification of implementation and effectiveness
 - May require environmental monitoring as part of the verification process



Slide 35

In summary, it is important to understand that sanitation controls are a type of preventive control and that use of this type of preventive control differs from Sanitation CGMPs. The intent of sanitation controls is to maintain clean animal food contact surfaces and prevent cross-contamination of undesirable microorganisms into finished animal food. Sanitation controls require monitoring, corrective actions and corrections, and verification of implementation and effectiveness. Typically, correction is utilized more frequently than a corrective action for sanitation controls, and environmental monitoring may be an appropriate verification activity.

This concludes the focus on sanitation controls. The next chapter will describe the final type of preventive control, a supply-chain-applied control.

NOTES

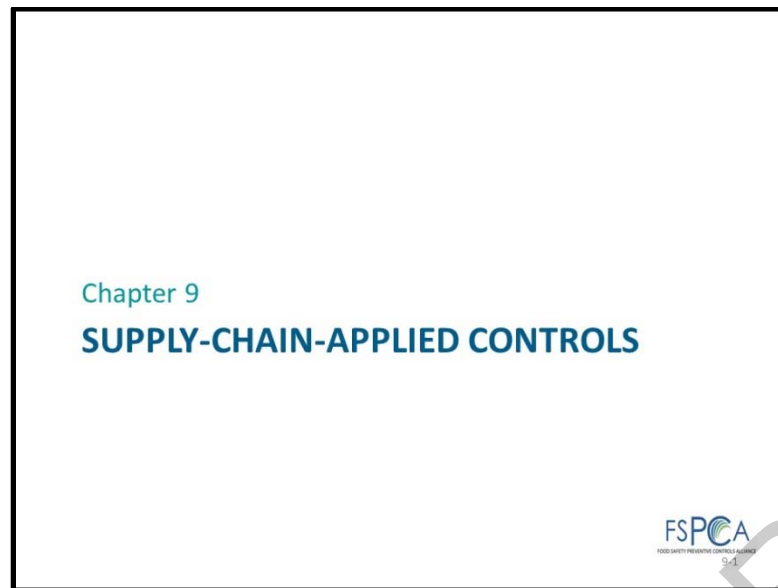
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

Chapter 9. Supply-Chain-Applied Controls



Slide 1

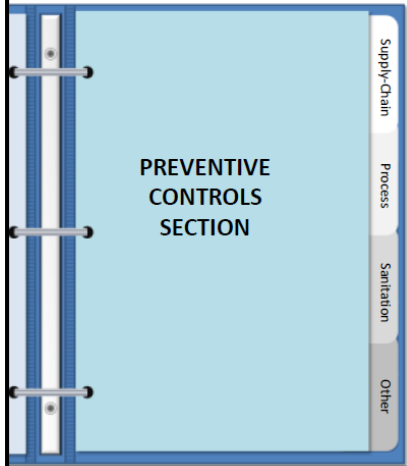
The safety of a product depends on much more than just what is controlled within the facility. Known or reasonably foreseeable hazards associated with a raw material or ingredient that a manufacturing facility receives may require a Supply-Chain-Applied Control to ensure its safe use. In this chapter, the terms “Supply-Chain-Applied Control” and “Supply-Chain Program” refer to requirements in 21 CFR 507 Subpart E – Supply-Chain Program in the *Preventive Controls for Animal Food* rule.

Companies may have extensive supplier programs that encompass much more than food safety elements to manage their supplier expectations and performance. This chapter focuses on the requirements of the regulation for verifying measures for control of hazards prior to receipt and not a company’s other supplier efforts.

The Supply-Chain Program described in this chapter is not the same as a supply chain program typically thought of by the animal food industry. In fact, Supply-Chain-Applied Controls may have limited applicability to animal food. The predominant application of Supply-Chain-Applied Controls is expected to be for the control of chemical hazards. Facilities that utilize Supply-Chain-Applied Controls must communicate to their supplier the importance of the preventive control since it will be applied by the supplier.

In the context of this curriculum, Supply-Chain-Applied Controls are the same as supplier controls. The Supply-Chain Program is outlined in Subpart E of the *Preventive Controls for Animal Food* rule.

Supply-Chain-Applied Controls Objectives



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

FSPCA
FOOD SAFETY PROGRAM CENTER
9-2

For simplicity, the term *ingredients* may be used in place of the phrase “raw materials and other ingredients” used in the regulation.

If applicable to your operation, see the Foreign Supplier Verification Program requirements on FDA’s website.

See the FSPCA website for information on the FSPCA Foreign Supplier Verification training program.

Slide 2

In this chapter, participants will learn the purpose of Supply-Chain-Applied Controls, and their role in an animal Food Safety Plan. The Supply-Chain Program relies heavily on key definitions of terms, such as supplier and receiving facility, so those will also be described. The requirements of the Supply-Chain-Applied Controls, as well as associated documentation, will also be covered.

Special requirements for *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* are not covered in this chapter. However, if a facility imports food products or ingredients it will also need to comply with the requirements as described in the FSVP. Regardless of whether ingredients come from a U.S. or a foreign supplier, the principles with respect to food safety are the same.

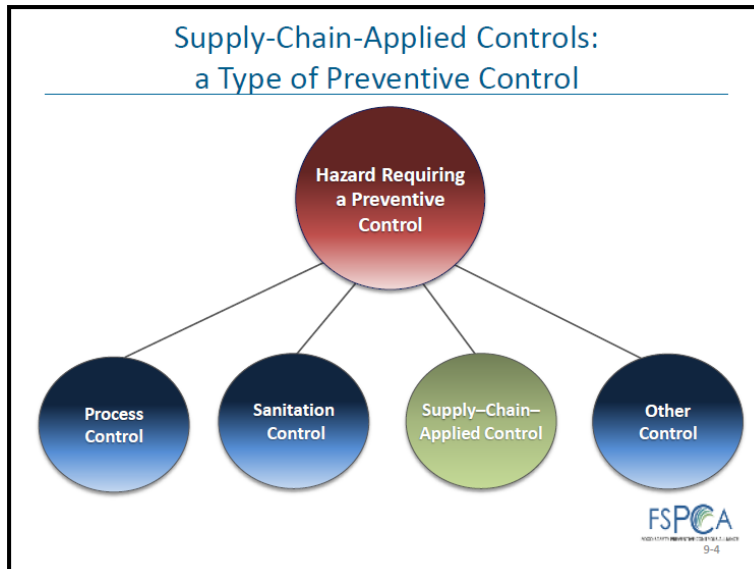
21 CFR 507, Subpart E – Supply-Chain Program

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



Slide 3

A Supply-Chain Program is a type of preventive control. While the requirements for process and sanitation preventive controls are found in subpart C, the requirements for a Supply-Chain-Applied Control are established in a separate subpart. Subpart E, Supply-Chain Program includes eight sections. These sections describe the requirements of a Supply-Chain Program including the responsibilities of the receiving facility, conducting supplier verification activities, and records used to document the program.



Slide 4

As discussed in Chapter 5, 21 CFR 507.34 introduces the concept of and basic requirements for preventive controls. Recall that a preventive control is required only when the facility has identified a hazard requiring a preventive control. Preventive controls are required to significantly minimize or prevent such hazards. Supply-chain controls are listed as a type of preventive control.

21 CFR 507.3 - Definitions: "Receiving Facility"

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



Slide 5

There are multiple definitions that are relevant to the Supply-Chain Program. The first two definitions covered in this chapter, receiving facility and supplier, describe “who” does what in the supply-chain program.

A receiving facility is “*A facility that is subject to subparts C (Hazard Analysis and Risk-Based Preventive Controls) and E (Supply-Chain Program) of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.*” While the *Preventive Controls for Animal Food* rule applies to facilities that manufacture, process, pack, or hold animal food, a receiving facility must be a manufacturer and/or processor.

21 CFR 507.3 - Definitions: "Supplier"

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



Slide 6

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

Participants should note that the supplier, by definition, is not necessarily the last establishment in the distribution chain that supplies the ingredient to the receiving facility or the entity that ingredients are purchased from. Rather, the establishment that last performed an activity on the material or ingredient is considered to be the supplier.

21 CFR 507.3 - Definitions:
"Supply-Chain-Applied Control"

- A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.



Slide 7

The third key definition is for a "Supply-Chain-Applied Control," which is "*A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.*" The two key items to note in this definition are that this is a type of preventive control, meaning it will need to significantly minimize or prevent a hazard, and that the application of the preventive control occurs before receipt by the receiving facility. These definitions, as with all others, are found in 21 CFR 507.3, which begins on page 56338 of the *Preventive Controls for Animal Food* rule.

When is a Supply-Chain Program Required?

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



Slide 8

During the hazard analysis process, the facility must first identify a hazard requiring a preventive control in a raw material or other ingredient. During the hazard analysis and preventive controls determination process, the facility determines if a Supply-Chain-Applied Control is necessary to control an identified hazard requiring a preventive control. This type of preventive control is only necessary if the agent is a *hazard requiring a preventive control* and the receiving facility needs a supplier to control the hazard. Supply-chain applied controls are typically used in situations where a hazard requiring a preventive control may be present in an incoming material or raw ingredient and the facility will not be using another type of preventive control (such as a process control) to control the hazard itself.

The hazard analysis may indicate that an ingredient and its supplier do have an association with a specific food safety hazard but the receiving facility doesn't establish a supply-chain applied control. In this case, a supply-chain program would not be required if a preventive control for the hazard is implemented within the receiving facility. For example, if a pathogen that is associated with an ingredient is controlled by implementing a validated kill step, the facility does not need a supply-chain program.

When is a Supply-Chain Program NOT Required?

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



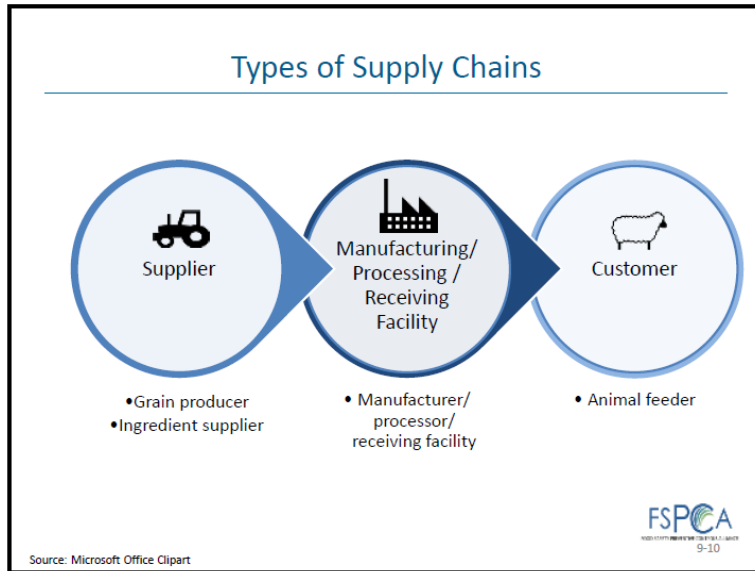
In order to not implement a Supply-Chain-Applied Control due to the food's use for research or evaluation, the following must occur:

- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled "Food for research or evaluation use;"
- The food is supplied in a small quantity consistent with a research, analysis, or quality assurance purpose, it is used only for that purpose and unused food is properly disposed of; and
- The food is accompanied with documents stating that it will be used for research or evaluation and cannot be sold or distributed to the public.

Slide 9

A supply-chain program is NOT required in the following situations:

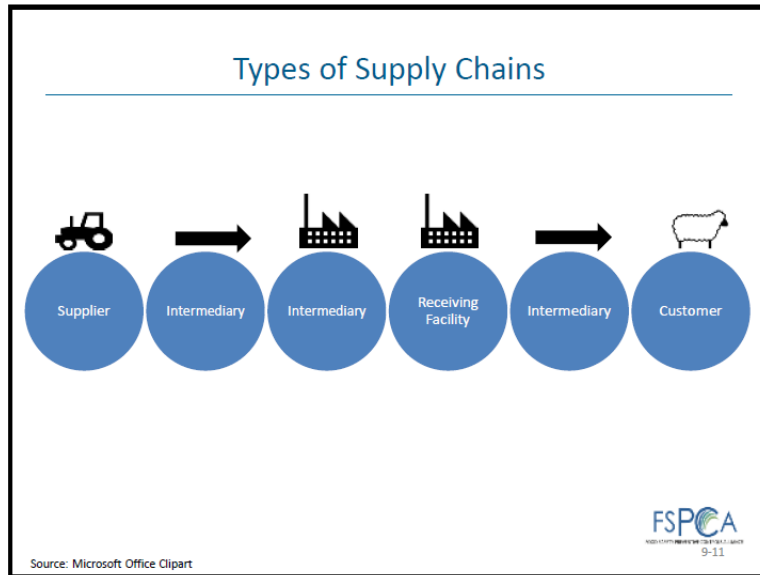
1. The hazard analysis concludes that the hazard is not a *hazard requiring a preventive control*
2. The receiving facility controls the hazards requiring a preventive control within the facility such as with a process or sanitation control
3. When a customer or downstream entity controls the hazard (see Slides 5-24 and 5-25 for a discussion on customer control of the hazard)
4. When an importer of the raw material or other ingredient is in compliance with the FSVP
5. The animal food is supplied for research or evaluation use (for example, if an animal food is produced solely for the purpose of evaluating the effectiveness of a new product on animal performance)



Slide 10

To understand the requirements of the Supply-Chain Program, it is important to understand the definitions of supplier and receiving facility in the context of the regulation.

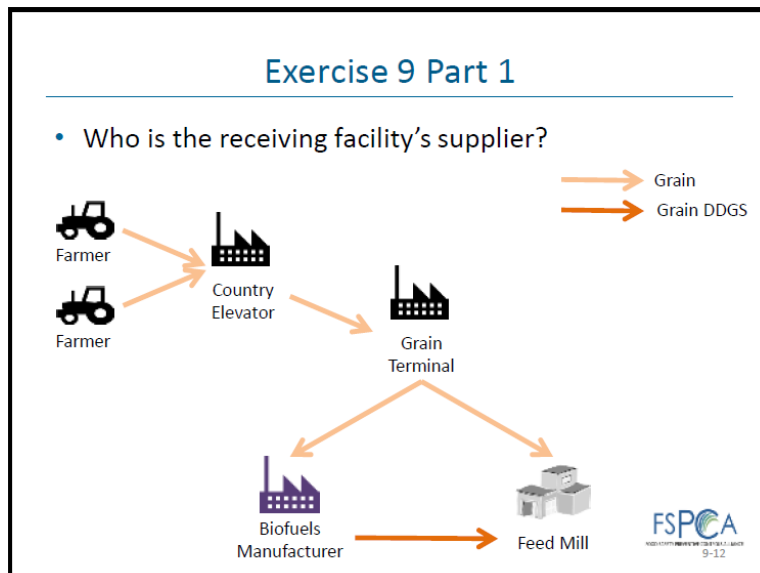
The example shown here is the most recognized version of a supply chain, with an ingredient supplier, a manufacturer, and an animal feeder as the customer. In this case, the manufacturer/processor is the “receiving facility” for a raw material or other ingredient. A “supplier” may be a manufacturer or processor of the material or ingredient received. Note that for incoming raw agricultural commodities (such as corn, oats, or soybeans), the “supplier” is the entity that grows the food (farmer) if no further processing of the ingredient occurs. An entity holding or transporting the ingredient is not the supplier unless some processing activity occurs while the ingredient is in their possession. It is also important to keep in mind that farms and facilities engaged in holding (such as some grain elevators) of raw agricultural commodities may be exempt from the *Preventive Controls for Animal Food* rule.

**Slide 11**

In reality, most supply chains are much more complex than the previous example as there are often intermediaries between an ingredient supplier, the receiving facility, and the ultimate customer (animal feeder). In this example, the supplier is a vitamin manufacturer. The supplier sells his product to a broker (the first intermediary) that does not take possession of the vitamin. The broker sells the product to another entity (second intermediary) that re-labels the vitamin. Because this entity does not conduct additional manufacturing/processing and simply re-labels the product, this person is not considered a “supplier” by definition in 21 CFR 507.3. The second intermediary sells the product to the receiving facility which uses the vitamin to manufacture animal food. The receiving facility then sells the product to a different broker (third intermediary), who does not take possession of the product. The broker then sells the product to the customer who feeds the animal food.

In the example above, the receiving facility is the animal food manufacturer. Although the receiving facility purchased the product from the second intermediary, under the definitions for the supply-chain program provisions the facility’s “supplier” for the vitamin ingredient is the vitamin manufacturer because that is the last entity that manufactured the animal food without further processing.

When a facility is considering the implementation of a supply-chain-applied control, the facility must consider the practicality of such a control for their facility and must be able to identify (and approve) their supplier. Identifying the supplier may be difficult depending on the commodity (e.g. suppliers for raw agricultural commodities may be more difficult to identify than suppliers of manufactured ingredients).



Slide 12

Exercise Part 1. This activity will help participants determine who are considered suppliers to a receiving facility. This is important for determining which facilities the receiving facility must approve as suppliers and conduct supplier verification activities.

Summary of Exercise 9 Part 1

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



Slide 13

The supplier is the establishment that manufactures or processes the animal food, raises the animal, or grows the animal food without further manufacturing or processing by another establishment. This is true, even if the supplier and/or any intermediaries are exempt from all or portions of the *Preventive Controls for Animal Food* rule.

Basics of a Supply-Chain-Applied Control

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



Slide 14

A supply-chain-applied control is used as a preventive control when the supplier controls the hazard in its ingredient or raw material before receipt of the ingredient or raw material by a receiving facility.

The receiving facility is ultimately responsible for implementing the supply-chain program and ensuring that hazards in the raw materials or other ingredients are controlled by the supplier.

The supply-chain program must be written (21 CFR 507.110) and would be considered part of the facility's Food Safety Plan (21 CFR 507.31(b)(3)).

Basics of a Supply-Chain-Applied Control

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



Slide 15

To meet Subpart E requirements, the supply-chain program must include:

1. Approving suppliers
2. Using only approved suppliers
3. Having written receiving procedures that the receiving facility follows and documents to ensure they only receive raw materials or other ingredients from approved suppliers
4. Determining, conducting, and documenting appropriate supplier verification activities
5. Implementing appropriate preventive control management components to ensure effectiveness of supply-chain applied control
6. Documentation to meet the recordkeeping requirements associated with the supply-chain program

Basics of a Supply-Chain-Applied Control

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



In most cases, brokers and distributors are not receiving facilities as defined in this rule. Thus, they cannot approve suppliers – that is an activity only the receiving facility can conduct.

The requirement for a receiving facility to “approve suppliers” may make supply-chain applied controls more challenging for animal food manufacturing facilities to implement compared to other preventive controls because bulk animal food is often supplied through brokers and distributors.

Slide 16

The receiving facility is the sole entity that can approve suppliers. Before receiving a raw material or other ingredient that requires a Supply-Chain-Applied Control, the receiving facility must approve the supplier and document the approval. While there is flexibility given to performing other components of the supply-chain program, only the receiving facility can approve suppliers.

Once the receiving facility has approved suppliers, they must take measures to ensure they only use raw materials and other ingredients from their approved suppliers. Using only approved suppliers ensures that the receiving facility only receives material from an entity that it has verified can control the hazard requiring a preventive control.

However, it is realistic to assume that there will be times when an ingredient is needed, but no approved supplier is able to provide it. Understanding this possibility, the rule allows, on a temporary basis, for the receiving facility to receive an ingredient from an unapproved supplier. In these cases, the received ingredient must be subjected to appropriate verification activities before use.

In cases where delivery of an ingredient is significantly delayed (such as in cases of severe weather), materials may be received from unapproved suppliers when those materials are subjected to appropriate verification activities.

Basics of a Supply-Chain-Applied Control

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



Slide 17

To ensure that the receiving facility only uses ingredients from an approved supplier, the receiving facility must have written procedures for receiving raw materials and other ingredients (see definition on slide 9-18), ensure these procedures are being followed, and document they are being followed.

The receiving facility has flexibility to design appropriate written procedures for receiving raw materials and other ingredients that are tailored to their facility and operations. The goal of these written procedures is to ensure that they can accurately identify approved suppliers and incorporate changes to suppliers in a timely and accurate way. These written procedures allow consistent implementation of the supply-chain program by personnel who order raw materials and other ingredients, personnel who receive raw materials and other ingredients, and personnel who conduct supplier verification activities.

The receiving facility is responsible for ensuring that the supply-chain program has these written procedures developed, that the procedures are being implemented, and that there is documentation to show that procedures are being followed. The receiving facility may choose to take on this responsibility itself, or the receiving facility can rely on another entity (such as a broker or distributor) to conduct these activities. If the receiving facility relies on another entity to conduct this activity, they must review the documentation (and document the review) to verify that the written procedures are being followed.

21 CFR 507.3 - Definitions: "Written Procedures for Receiving Raw Materials and Other Ingredients"

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



Slide 18

In other areas of the curriculum, written procedures are discussed as being necessary to demonstrate that proper actions are taken to protect animal food safety. For the supply-chain program, there is a specific definition for written procedures for receiving raw materials and other ingredients. These are *"written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use)."*

Supply-Chain-Applied Controls

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



Slide 19

Once approved suppliers are identified and receiving procedures written, the receiving facility must identify and implement appropriate verification activities to ensure that the supplier actually controls the hazard requiring a Supply-Chain-Applied Control.

The receiving facility must determine one or more of the following verification activities that must be conducted before initial use of the raw material or ingredient and periodically thereafter.

- Onsite audit (See slide 9-23)
- Sampling and testing (See slide 9-25)
- Review of the supplier's relevant food safety records, such as the Food Safety Plan or processing temperatures (See slide 9-26)
- Other verification activities deemed appropriate based on the risk associated with the ingredient and the supplier (See slide 9-26)
 - The rule provides for alternate supplier verification activities if the supplier is one of three types of entities. If a supplier is a Qualified Facility, a small produce farm, or shell egg producer with less than 3,000 laying hens, the alternate supplier verification activities are limited and involve obtaining certain attestations. These circumstances are described in 21 CFR 507.110.

In addition to determining the appropriate types of supplier verification activities, the receiving facility must also determine the frequency that the verification activities need to be conducted. There are several factors that must be taken into consideration when determining what is an appropriate supplier verification activity (see slide 9-22).

Verification is usually not conducted at the same frequency as monitoring activities. Typically, verification is conducted after preventive controls have been applied as a check that the system is operating according to the Food Safety Plan. While some verification activities are performed for each lot (e.g., records review for in-house preventive controls), some supplier verification activities could be performed at a reduced frequency, depending on many factors, including the nature of the hazard and supplier performance.

Supply-Chain-Applied Controls

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



Slide 20

Once the facility has identified the appropriate types and frequency of verification activities, they are responsible for making sure these activities are conducted. A receiving facility can conduct these activities themselves. However, a receiving facility can instead rely on another entity, such as a broker or distributor, to determine the appropriate supplier verification activity and/or conduct supplier verification activities provided that the receiving facility reviews and assesses the entity's applicable documentation.

While a receiving facility can rely on another entity to determine and conduct supplier verification activities; there are restrictions on what suppliers can do for the receiving facility. The receiving facility cannot rely on a supplier's determination of appropriate verification activities for its own product – the receiving facility needs to determine appropriate verification activities that are consistent with the animal food being produced. A supplier's self-audit or a supplier's review of their own records are not appropriate supplier verification activities. However, a supplier can provide an audit conducted by a third-party qualified auditor if the receiving facility has determined this is an appropriate verification activity for that animal food. Sampling and testing is the only supplier verification activity a supplier can conduct for the receiving facility, provided the receiving facility has determined that this is an appropriate verification activity for that animal food.

Regardless of the type of verification activity, it must be completed before using the raw material or other ingredients, and periodically thereafter.

Ultimately, it is the responsibility of the receiving facility to ensure that the Supply-Chain Program provides assurance that a hazard requiring a preventive control has been significantly minimized or prevented.

Supply-Chain-Applied Controls

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



Slide 21

Finally, the activities associated with both the determination and conduction of the supply-chain program must be written. As with all records that support the Food Safety Plan, they must meet the recordkeeping requirements set out in Subpart F.

Factors for Supplier Approval and Verification

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



Slide 22

The rule lays out specific considerations that must be taken into account when approving suppliers and determining appropriate verification activities, including frequency. The receiving facility must consider:

- The results of the hazard analysis, which gives an indication of the risk posed by the hazard
- The specific entity applying the controls
- The supplier's performance, such as procedures, processes, and practices related to food safety, compliance with applicable FDA food safety regulations, and food safety history
- Other factors, as appropriate and necessary, such as the storage and transportation of the raw materials or ingredients

Onsite Audit Requirements (21 CFR 507.35)

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



SAHCODHA hazards are hazards for which there is a “reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.” See chapter 3 for additional discussion on SAHCODHA hazards.

For a SAHCODHA hazard, the audit must be conducted before receiving an ingredient and at least annually thereafter.

Some companies use their own qualified employees to audit suppliers. Such audits allow first hand review of the critical food safety programs and preventive controls in place at the site. One can obtain a sense for how effective programs are by diligently reviewing program records, observing activities, and interviewing line workers.

While this type of audit allows a company to verify that their specific requirements are being met, it requires internal resources and expertise that may not be feasible for some companies. Audits conducted by an independent third party may also be used. Your supplier may be able to provide a third-party audit for your review.

Slide 23

There is not a requirement for an annual onsite audit except when the hazard is a SAHCODHA hazard (a PCQI may provide written a written determination that other activities and/or less frequent auditing is adequate for the SAHCODHA).

Any audit conducted under the supplier verification program must be conducted by a qualified auditor (defined on slide 9-24). Audits include both records review and observation of practices. A comprehensive systems audit that includes records review is more likely to reflect conditions throughout the year than an audit focused only on the state of the facility at the time of the audit.

The audit must address process, sanitation, and supply-chain-applied controls, as well as CGMPs, as applicable. In addition, the audit must address, where applicable, relevant FDA food safety regulations, the supplier's written plan, and the implementation of the written plan. Lastly, the audit must address the specific hazards identified in the receiving facility's hazard analysis. Some suppliers are routinely inspected by FDA or other recognized agencies. Thus, the receiving facility may be able to rely on the results of these inspections instead of a private party audit and obtain information on these inspections annually from the supplier. If used, such an inspection must be “appropriate” and be conducted for compliance “with applicable FDA food safety regulations.” In other words, the inspection must be sufficiently relevant to an onsite audit to be considered a credible substitute. Keep in mind that these inspections may not occur annually, and there is a requirement that an audit used in this way will have been conducted within one year of when an on-site audit would have been required.

21 CFR 507.3 - Definitions: "Qualified Auditor"

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



The "part 1, subpart M" referred to in this definition is the Accredited Third-Party Certification rule.

Slide 24

The definition of a qualified auditor is: *A person who is a qualified individual and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential auditors include:*

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter"

Sampling and Testing

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



Slide 25

Testing of in-process materials, environmental samples, or the ingredient produced by the supplier may be appropriate as a verification activity if such testing provides meaningful results related to control of a hazard requiring a preventive control. Testing can occur at the supplier's facility, at an outside laboratory, or at the receiving facility. This test information would be captured in a Certification of Analysis (COA). When using sampling and testing, it is important to use methods that are fit for purpose and that the limitations of testing due to sampling probability are understood. The approach should depend on the potential hazards and the controls in place for the specific product. Testing for new supplier approval is usually more extensive than for maintenance of approved supplier status.

It is advisable to consult a reference book, a technical expert or other credible source to determine appropriate testing and sampling plans. Appropriate references may vary depending on types of food products and any related hazards identified. In some situations, references may identify indicator tests which might prove to be more useful to verify process control than specific pathogen testing. This may be the case when an indicator test provides more rapid results and is less expensive to conduct.

Other Verification Activities

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



Slide 26

The PCQI may determine that other activities may be useful for supplier approval and verification depending on the hazards being managed. Companies may require their vendors to provide a Continuing Product Guarantee certifying that the product meets company requirements, including legal, regulatory, and conformance to specifications. These certificates generally cover multiple shipments or timeframes and should be reviewed and renewed at least annually or when requirements change. These generally do not serve as verification activities in the way that audits or testing (e.g., COAs) do, but may be suitable for certain ingredients, such as those with frequent government inspection. Further, they would not be the sole verification activity for compliance with the regulatory requirements. Copies of production records could also be reviewed to verify that the hazards were controlled and that material was produced to specifications.

Basics of a Supply-Chain-Applied Control

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



Slide 27

The receiving facility must implement appropriate preventive control management components to ensure a supply-chain-applied control is effective in controlling an identified hazard. The preventive control management components for a supply-chain applied control should be appropriate for the hazard. (See slide 9-20)

There are numerous documentation requirements associated with the supply-chain program in the rule. (See slide 9-30)

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

Slide 28

Preventive control management components were introduced in Chapter 6. As noted in 21 CFR 507.39, found on page 56347 of Appendix I, the Supply-Chain Program is subject to corrective actions and corrections and verification of implementation and effectiveness, specifically including a review of records of calibration, testing, and supplier and supply-chain verification activities. The use of the preventive control management components for a Supply-Chain Program should be as appropriate to ensure the effectiveness of the Supply-Chain Program and take into account the nature of the hazard controlled before receipt of the ingredient.

Corrective Actions

- Written corrective action plan and records required
 - Identify and correct the problem
 - Reduce the likelihood that the problem will recur
 - Evaluate all affected animal food for safety
 - Prevent affected animal food from entering commerce, as necessary
 - Reanalyze the Food Safety Plan when appropriate



Slide 29


Corrective actions were introduced in Chapter 6 during the discussion of preventive control management components. For a Supply-Chain-Applied Control, corrective actions may be unique, given that they may very well occur outside of the facility.

When an audit or other verification activity identifies a gap in supplier performance related to a hazard requiring a preventive control, the receiving facility must ensure that the animal food being manufactured is not adulterated as a result of the supplier not adequately controlling the hazard. Corrective actions will vary depending on the issue as previously discussed in the other chapters on process and sanitation preventive controls.

Because system failures can occur in the supplier's process or procedures from time to time, the supplier must have a corrective action process for making modifications to prevent reoccurrence of an issue. The receiving facility must ensure that the intended corrective action is actually implemented. In addition, there must be an evaluation of all affected product for food safety to ensure that adulterated food does not enter into commerce. If adulterated product did enter commerce, then a recall would be required (see Chapter 10: Recall Plan).

Summary of Records Required to Document the Supply-Chain Program

<ul style="list-style-type: none"> • Supply-chain program • Compliance with foreign supplier verification program (if applicable) • Supplier approval • Written procedures for receiving raw materials and other ingredients • Demonstrated use of written procedures for receiving raw materials and other ingredients • Determination of appropriate supplier verification activities • Determination that activity other than an onsite audit and/or less frequent audits are adequate 	<ul style="list-style-type: none"> • Written results of an appropriate inspection by FDA or other agency when inspection substituted for an onsite audit • Verification of control applied by an entity other than the direct supplier • Facility's review and assessment of other entity's documentation • Onsite audit report • Sampling & testing results (if applicable) • Review of supplier's relevant food safety records • Other verification activities based on supplier performance and material risk • Corrective action plan and records
--	---



Slide 30

This slide is a summary of the key required documents for the supply-chain program, if applicable, to the facility's program. Without records, one cannot demonstrate supplier programs are implemented as designed and are effective in controlling hazards.

The documentation requirements start with the written Supply-Chain Program or documentation of compliance with the foreign supplier verification program (if applicable).

The facility must maintain documentation of approval for those suppliers that provide ingredients requiring a Supply-Chain-Applied Control. The receiving facility must also have written procedures for receiving raw materials and ingredients and maintain records that demonstrate that all raw materials and other ingredients with hazards requiring a Supply-Chain-Applied Control are received from approved suppliers, unless a specific exception applies as described previously.

The facility must document the determination of the appropriate supplier verification activities that will be conducted for raw materials and other ingredients requiring a Supply-Chain-Applied Control. Onsite audits, sampling and testing, review of supplier's relevant food safety records, or other approaches may be identified.

Records are necessary for all verification activities being conducted to ensure the supply-chain-applied is working. If verification activities other than those above are used, they must also be documented. Corrective actions, if any, must also be documented in response to the detection of hazards through sampling and testing.

Not all of these documents will be required for every facility's supply-chain program. If a facility does not include a component in their supply-chain program, such as onsite audits, the facility would not be required to maintain records associated with the onsite audit.

Good Supply-Chain Business Practices

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



These are good business practices, but not all are required by the *Preventive Controls for Animal Food* rule. The rule requires review and reanalysis of the Food Safety Plan at least once every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

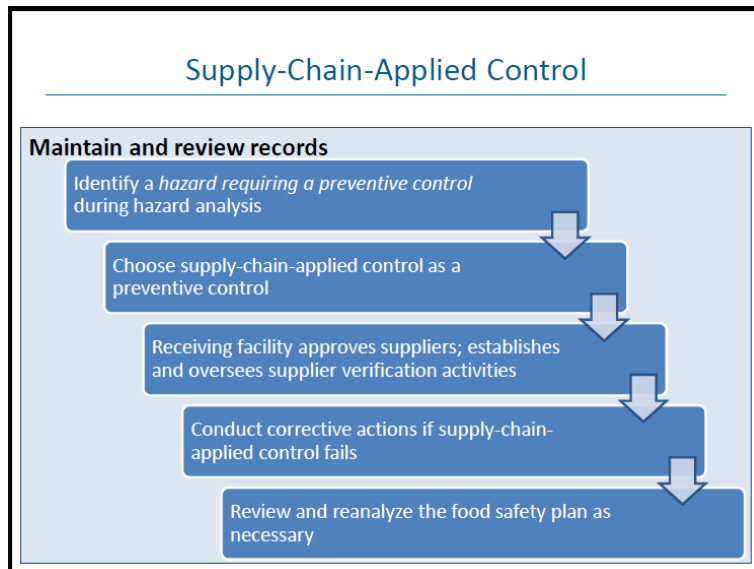
Slide 31

Change is a necessary part of the business process. Having procedures in place to accommodate changes can help avoid food safety or potentially disruptive supply-chain issues. Two aspects of change should be considered relative to suppliers – changes made by the supplier and changes made by the receiving facility. If suppliers make a change to the ingredients that they provide, the food safety team should be informed to allow reanalysis to determine if changes are needed to the Food Safety Plan or supply-chain program. Frequently supplier communications are handled by purchasing; thus, the purchasing team must forward relevant information to the food safety team. The supplier should understand the importance of reporting all changes to customers so they can analyze the change with respect to their use of the ingredient. Conversely, the receiving facility and/or its purchasing team may identify a new supplier that can provide a similar ingredient. It is essential that purchasing not make a switch in suppliers of an ingredient or raw material associated with a hazard requiring a supply-chain-applied control without the authorization of the food safety team. The new supplier must be approved if the ingredient is associated with a hazard requiring a supply-chain-applied control.

It is a good business practice to evaluate the supply-chain program on a routine basis (typically annually) as suppliers may change their processes, your facility may create new formulations, or new hazards may arise. Comparing findings from the supplier approval, verification, and corrective action processes against the safety requirements in the supplier specifications and contract may indicate the need for change.

If a food safety issue occurs with a product, there should be a review of the supply-chain program, including verification activities, to ensure that program inadequacy was not the cause. For example, the program may not have identified a hazard that is associated with an ingredient that needed to be controlled by the supplier. Also verify that the supplier took steps to prevent recurrence of issues, when applicable.

Reanalysis of the Food Safety Plan may also be relevant for company-initiated supplier changes, especially those for ingredients with hazards requiring a preventive control. Reanalysis of the Food Safety Plan may be required if there is an identified failure of a supply-chain applied control.



Slide 32

This slide summarizes the Supply-Chain-Applied Control. The major components of the program are:

- The hazard analysis identifies a hazard requiring a preventive control.
- A Supply-Chain-Applied Control is chosen as the appropriate control.
- The receiving facility establishes and conducts supplier verification activities.
- If any deficiencies are identified, corrective actions are implemented.
- The Supply-Chain Program undergoes review and reanalysis. The need for review and reanalysis may arise as necessary, due to time since the last review, implemented corrective actions, or new information becoming available.
- Review and reanalysis may lead to further hazard analysis, thus restarting the cycle.

For all of these actions, records must be generated, maintained, and reviewed in accordance with requirements established in the *Preventive Controls for Animal Food* rule.


**Slide 33**

The following slides provide an example of how a Supply-Chain-Applied Control may be utilized in a Food Safety Plan. To demonstrate these concepts, we will pick back up with the copper toxicity example first described in Ch. 5 and 6 in the Example Food Safety Plan for Multi-Species Medicated and Non-Medicated Feeds.

Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill		ISSUE DATE X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES X / Y / 2015

Table 1. Hazard Analysis		
Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards	
Ingredients	C	Copper toxicity




9-34

Slide 34

In the example plan, copper toxicity is a known or reasonably foreseeable chemical hazard if the sheep mineral premix is received with an incorrect copper concentration.

Livestock Food Example				
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds			PAGE X of Y
PLANT NAME	ABC Feed Mill		ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	X / Y / 2015

Table 1. Hazard Analysis				
Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Copper toxicity in sheep	I – High	B - Medium	Yes	Multispecies premises used by facility, copper toxic to sheep




Slide 35

In Chapter 5, the determination of severity and probability was discussed. Because excess copper can be extremely toxic to sheep and the facility uses multiple premises, it was determined that the hazard required a preventive control. The extreme toxicity can lead to death in sheep, and so the facility considers this to be a SAHCODHA hazard.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill		ISSUE DATE X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES X / Y / 2015

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




9-36

Slide 36

The facility receives multiple trace mineral premixes, all purchased from the same supplier. With this being the case, the facility determined that the appropriate preventive control is a Supply-Chain-Applied Control to ensure that the incoming sheep trace mineral premix does not contain excess copper. This could potentially happen if a mixing or sequencing error occurred at the supplier. This is Preventive Control #1 identified in the example Food Safety Plan.

Livestock Food Example				
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y	
PLANT NAME	ABC Feed Mill		ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	X / Y / 2015

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




9-37

Slide 37

Table 2 identifies the preventive control category as being a Supply-Chain-Applied Control. There are no parameters (minimum or maximum values) associated with Supply-Chain-Applied Controls because the control is applied at the supplier and not at the facility, Thus, 'n/a' for 'not applicable' is placed in the table.

Livestock Food Example				
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y	
PLANT NAME	ABC Feed Mill		ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA		SUPERSEDES	X / Y / 2015
Table 2. Description of Preventive Controls				
Preventive Control(s)	Management Components			
(1)	(6)			
Hazard Requiring a Preventive Control	Monitoring (if applicable)			
	What	How	Frequency	Who
Copper toxicity in sheep	n/a	n/a	n/a	n/a



 9-38

The monitoring row has n/a for not applicable because this example is for the receiving facility. Monitoring is not a required management component for receiving facilities if controlling a hazard through a supply-chain applied control. Instead, the monitoring is conducted by the supplier.

Slide 38

Supply-Chain-Applied Controls are not subject to the preventive control management component of monitoring. Thus, n/a is placed in the monitoring section of the table.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015
Table 2. Description of Preventive Controls			
Preventive Control(s)	Management Components		
(1)	(7)	(8)	
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records	
Copper toxicity in sheep	If improper Cu concentration in premix was used: 1) identify root cause, 2) re-train employee(s), 3) determine scope of problem by evaluating records and/or sampling and analyzing animal food, when necessary, 4) either blend, divert, hold-and-test, or dispose of affected animal food to prevent it from entering commerce, 5) reanalyze the Food Safety Plan, if necessary.	COA from supplier; Records reviewing the COA by supplier; Supplier approval and verification documentation; Record of annual audit	

9-39

Slide 39

Every incoming lot of sheep trace mineral premix must be accompanied by a Certificate of Analysis (COA), demonstrating that the premix contains an accurate copper concentration for sheep. This COA is to be the result of test-and-hold procedures at the supplier. If the COA is not present, the shipment must be rejected. If a failure occurs, and a shipment is erroneously accepted, the disposition of the premix must be determined, and the recall plan initiated if necessary.

In addition to the applicable COAs and records of their review, records are also generated and retained in accordance with supplier approval and verification requirements. This includes the approved status of the supplier, as well as records of annual third-party audits of the supplier due to copper toxicity being considered a SAHCODHA hazard.

Livestock Food Example			
Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds	PAGE X of Y	
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 3. Description of Preventive Control Verification Activities	
Activity	Description of Activity
Type of Validation	n/a
Supplier Verification Activities	<ul style="list-style-type: none"> Onsite audit Uses COAs for assurance of incoming Cu concentration Quarterly analysis of sheep trace mineral premix by the supplier to verify proper copper levels do not exceed the values established through the supply-chain-applied control via a certificate of analysis Reviewing the records of the supplier's Food Safety Plan for sequencing and flushing procedures to prevent carryover of copper into the sheep trace mineral premix
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

Slide 40

There is no validation required for Supply-Chain-Applied Controls.

The verification activities include an onsite audit by the receiving facility because copper toxicity was identified as a SAHCODHA hazard. The facility also receives COAs with each batch of ingredient from the approved supplier. In addition, there is quarterly analysis of the sheep trace mineral premix by the supplier to verify proper copper levels and they do not exceed the value established by a certificate of analysis. There is also review of the records of the relevant parts of the supplier's Food Safety Plan (descriptions of the sequencing and flushing procedures used to ensure that copper carryover is prevented).

A reanalysis of the plan is conducted every three years, as necessary when changes occur, or when it is determined that a preventive control is ineffective.

Summary

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



Slide 41

In summary, the hazard analysis process identifies hazards requiring a Supply-Chain-Applied Control for which a Supply-Chain Program must be implemented. The supplier is the entity that manufactures or processes an ingredient, grows the food, or raises the animal that the receiving facility uses to make the product. There are key requirements that must be met if a receiving facility uses a supply-chain control to control a hazard, such as:

- Approving suppliers,
- Using approved suppliers,
- Having and using written procedures to ensure ingredients are only received from approved suppliers
- Conducting and documenting supplier verification activities
- Documentation.

NOTES

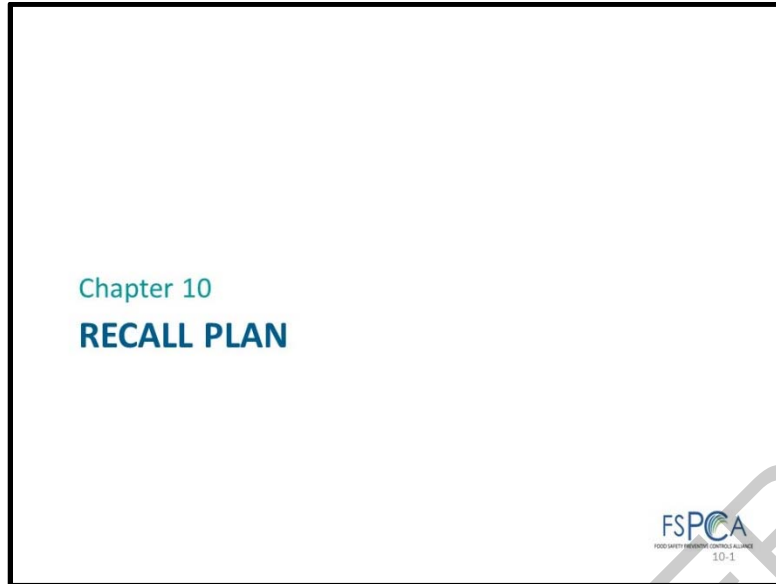
PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

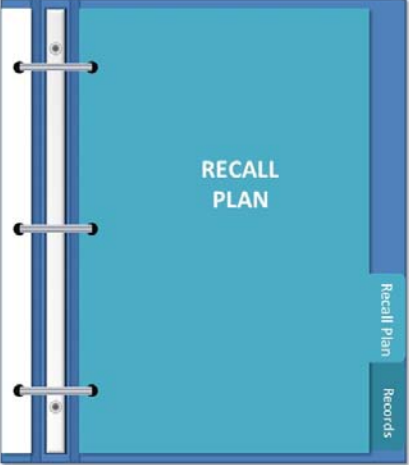
CHAPTER 10. Recall Plan



Slide 1

The *Preventive Controls for Animal Food* rule requires the development of a written Recall Plan when a hazard analysis identifies a *hazard requiring a preventive control*.

Recall Plan Objectives



In this module, you will learn:

- Recall definitions
- Elements of a recall plan
- Who to notify when a recall is necessary
- How to conduct effectiveness checks
- Appropriate disposition of product

FSPCA
10-2

Note that this chapter describes the requirements of a recall plan according to the *Preventive Controls for Animal Food* rule and some additional good industry practices. This chapter does not cover all the FDA requirements regarding recall situations.

An effective recall plan can reduce the financial impact for the company by facilitating rapid retrieval of an adulterated product. An effective recall plan can also reduce the impact of an animal food safety event.

Slide 2

This module reviews definitions of recall classes, required elements of a Recall Plan, who to notify when a recall is necessary, how to conduct effectiveness checks, and methods that can be used to dispose of affected product.

21 CFR 507.38 Recall plan

- (a) For animal food with a hazard requiring a preventive control you must:
 - (1) Establish a written recall plan for the animal food; and
 - (2) Assign responsibility for performing all procedures in the recall plan
- (b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:
 - (1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
 - (2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;
 - (3) Conduct effectiveness checks to verify the recall has been carried out; and
 - (4) Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

FSPCA
NATIONAL ANIMAL CARE ASSOCIATION
10-3

Slide 3

The rule requires that a facility that identifies a *hazard requiring a preventive control* must establish a written recall plan and assign responsibility for performing all the procedures in the recall plan. The written recall plan must describe actions as appropriate to conduct a recall. The actions required include:

- Direct notification of consignees about animal food that is being recalled and how to return or dispose of the animal food.
- Notification of the public about any hazard present in animal food to protect human and animal health, as appropriate.
- Conduct effectiveness checks with customers who received recalled product, which may include warehouses, distributors, or animal feeders, to verify that all affected customers have been notified.
- Disposition of recalled animal food through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food, as appropriate.

Recall Classifications

- Actions taken by a firm to remove a violative product from the market
 - **Class I recall:** reasonable probability of serious adverse health consequences or death
 - **Class II recall:** may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
 - **Class III recall:** not likely to cause adverse health consequences
- May be conducted on a firm's own initiative, by FDA or state request, or by FDA or state order



Public press releases are required for Class 1 recalls and sometimes for Class 2 recalls when there is a threat to public health of humans or animals. Decisions regarding when notification is necessary can be determined through discussions with FDA.

FDA has the authority to mandate a recall in Class I situations, but typically, a company voluntarily issues the recall notice. The mandatory recall authority is outlined in 21 CFR 7.40, which provides guidance on the policy, procedures, and industry responsibilities for conducting a mandatory recall.

Slide 4

Recalls are actions taken by an establishment to remove an adulterated, misbranded, or violative product from the market. If a company withdraws a product for quality issues or the product has not entered commerce, the actions are not usually considered a recall.

Three classes of recalls are defined based on the potential health effects.

- A Class I recall is the most serious and involves product that has a reasonable probability of causing serious injury, illness, or death.
- Class II recalls may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recalls are not likely to cause adverse health consequences, but are still in violation of the law.

Typically, a company voluntarily conducts a product recall, either on their own accord or at the request of FDA or a state. However, the Food Safety Modernization Act grants FDA mandatory recall authority to require a Class I recall, if necessary.

Recall Plan Requirements

- Required for any food with a hazard requiring a preventive control
- Must be written
- Must describe steps to take and assign responsibility to:
 - Notify direct customers and consignees
 - Notify the public, when appropriate
 - Conduct effectiveness checks
 - Execute disposition of food



Slide 5

A Recall Plan must be written and in place before a recall occurs to ensure that actions taken to recall an animal food are conducted efficiently and in a timely manner. A rapid response is especially important for Class I and Class II recalls for which public health is at risk.

The written Recall Plan must include procedures that describe the steps to take and assign responsibility for those steps. Some people can be assigned to multiple tasks, but their role should be defined in the Recall Plan to support a quick response. The required procedures include those outlined in Slide 3: the notification of customers, notification of the public, effectiveness checks, and the appropriate disposition of animal food.

Recall Plan Common Elements

- Defined roles and responsibilities
- Contact lists for external notification
 - Regulators, customers, public
- Lot identification and verification information
- Effectiveness check procedures during a recall
- Product disposition procedures



Slide 6

The rule is flexible and does not specify how a facility should carry out recall procedures, just that those procedures must be written. Examples of good industry practices that may be included in the Recall Plan are:

- Predefined roles and responsibilities;
- Procedures to determine if a recall is needed;
- Contact lists for external notification of regulators, customers, and the public;
- Lot identification descriptions;
- Effectiveness check procedures to be used during a recall;
- Forms to record information; and
- Draft notices to complete in the event of a recall.

A brief discussion of these common industry practices is outlined next.

Define Recall Roles

- Identify and document a recall coordinator and recall team
- Describe duties and roles of the team in the recall plan
- Recall team may include:
 - Recall coordinator
 - Preventive Controls Qualified Individual
 - Operations manager
 - Publicity and public relations
 - Sales and marketing
 - Logistics and receiving
 - Quality assurance
 - Accountant
 - Scientific advisor
 - Attorney
 - Administrative support
 - FDA recall coordinator
 - State recall coordinator



The recall coordinator should be someone who can devote full attention to the recall and keeping things organized.

Small companies may not have enough people to assign different people to each role.

Slide 7

The owner, operator, or agent in charge of a facility is accountable for the safety of the animal food, but this responsibility for overseeing recalls may be carried out by the *Preventive Controls Qualified Individual*. A recall coordinator may or may not be the PCQI. The coordinator, and when appropriate a recall team, are typically identified in the Recall Plan. The recall coordinator generally has the following duties:

- Directs all product recalls
- Directs the recall team and coordinates all actions and communications
- Ensures that all appropriate documentation relating to the manufacture and shipment of the affected product is collected; e. g., processing records, laboratory testing records, ingredient batch sheets, inventory reports, shipping manifests, depending on the incident
- Determines (e.g., from inventory management and shipping records) exact location and quantity of affected product involved in the recall
- Reports the status, findings and recommendations related to all product recall situations to senior management if they are not part of the recall team
- Notifies all pertinent regulatory agencies
- Maintains the establishment's written policy, Recall Plan, and all associated recall activities

The recall team should include all functions necessary to collect accurate and complete information. For example, production, shipping, quality assurance, sales and administrative personnel should be considered as members of the recall team. If the firm has multiple locations, the team may include corporate team members from different departments (e.g., safety, quality assurance, distribution, etc.). Each recall team member should have clearly defined roles.

Define and Assign Responsibility

- Define details of each step in the recall process and person responsible for each item
 - Scope of recall
 - Regulatory agency communication
 - Recall initiation
 - Customer notification
 - Information and data compilation
 - Document gathering
 - Securing inventory of affected lot(s) in your control
 - Product disposition
 - Documentation



Slide 8

The Recall Plan should define each step of the recall process and clearly describe what needs to be done and who is responsible for carrying out each task. Knowing this ahead of time and conducting mock recalls reduces confusion and helps to support an organized response. As an industry good practice, a mock recall may be helpful to conduct on an annual or semi-annual basis. The use of mock recalls will be discussed more thoroughly later in this chapter.

In the recall plan, all responsibilities should be clearly defined, such as who will initiate the recall and who will notify external customers. Clear documentation helps to define the extent of the recall. While several people may be involved in gathering different types of documents, compiling the information and data gathered ultimately should be done by one individual to ensure that a complete picture of the situation is available. Assign responsibility for each of the types of documents needed to ensure that everything is completed.

When recalls occur, some of the affected product may still be in the company's control. Other product may be in transit to or be in possession of customers. In addition to notifying customers, assign responsibility and define procedures for securing inventory that is still within the control of the company to avoid inadvertently shipping product that would be subject to a recall.

External Notification

- Notify regulatory agencies
 - FDA and state recall coordinator
- Contact customers affected by the recall
 - Identify product and how to return or dispose of it
- Notify the public when appropriate
 - Required for Class I and some Class II recalls



If a recall is deemed appropriate, the firm should contact the recall coordinator from their FDA District Office. This information is available from the FDA website and may be beneficial to include in your recall plan.

The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is reasonable probability that an animal food will cause serious adverse health consequences. Facilities must report food safety issues to FDA within 24 hours of determining that the issue presents serious health consequences. The RFR is also useful for investigating information on animal foods that have been reported.

FDA posts recall notices on their website. Model recall notices are also available, which may be used to create a draft recall notice for a facility's Recall Plan.

Slide 9

When it is determined that a recall is necessary, notify the appropriate regulatory agencies. In addition to notifying the FDA, many states have recall coordinators. It is useful to include their contact information in a Recall Plan.

The Recall Plan must include procedures for notification of outside customers/consignees who received product. Customers should be informed of the type of product, quantities of affected product they received, dates product was shipped and reason for the recall. Also tell customers to immediately put product on hold. Once information is gathered, product disposition will be determined, as well as effectiveness of the recall effort.

A press release is required for all Class I recalls, and in situations when the facility is not able to contact all of their direct consignees. In addition, a facility may choose to issue a press release with some Class II recalls. While a detailed press release cannot be developed until an incident occurs, a Recall Plan can include templates that describe the information that would be inserted and should identify where to send a press release if this is necessary. FDA policy gives the recalling firm the first opportunity to prepare and issue publicity concerning its recall. During a recall situation, the facility should work with the FDA to develop and approve the press release. The Agency has model press release examples available. If the FDA believes it to be necessary, the agency may issue its own press release announcing a firm's recall.

Identification and Verification of Lot Information

- Identify product involved in a recall
 - Outer packaging (where appropriate)
 - Feed tags (where appropriate)
 - Bulk shipments (where appropriate)
- Identify quantities of product involved in a recall
 - Facilitates metrics involved in the recovery of suspect product



Slide 10

Lots involved in a recall must be accurately identified. The method of identification may vary based on the type of animal food being produced and its method of production. For example, some lots may be broken by individual mixed batch, by truckload of bulk shipment, or by date of manufacture. For this reason, a good industry practice includes breaking the manufacturing of a product into small lots, when appropriate, to minimize the volume of product requiring recall.

Lots may be identified on outer packaging, on feed tags, or even on bulk shipment records. Regardless of how the product is identified, the information should be easily understood by all the stakeholders that receive this information during a recall investigation. Unclear or poorly identified lots hamper the effectiveness of any recall effort and increase the amount of time and resources needed to complete the recall. Lot records should be rapidly accessible.

All information should be cross checked for accuracy. Incomplete or erroneous information causes confusion and delays in transmitting information. Lack of organization can slow down the process. Accurate information is needed for government agencies and the facility to conduct a thorough and efficient recall.

Product Disposition

- Determined based on the hazard, the food and other factors
- May include
 - Reworking
 - Relabeling
 - Diverting to a use that does not present safety concern
 - Destruction
- Must be documented



Slide 11

The Recall Plan must include procedures that describe the steps taken to determine the appropriate disposition of the recalled product. Depending upon the hazard and the animal food, sometimes a product can be reconditioned to make it suitable for use as animal food. Diverting the animal food to another use may be an option as long as it does not create an animal food safety issue. For example, it may be possible for a sheep feed that contains a level of copper toxic to sheep to be fed to beef cattle, when appropriate, because beef cattle are not as sensitive to copper toxicity as sheep. Destruction of the animal food is the final option, and is sometime necessary. However, destruction should occur in a way to ensure the animal food is not used for an unintended purpose. For example, animal food that is packaged in bags should have the bags sliced open prior to composting to prevent unintended use for another animal.

Procedures for product disposition need to consider both product that is in-house (and thus under the establishment's control), as well as product that is returned from customers. In some cases, the firm may direct customers to destroy product instead of returning it. Such situations may be described in the Recall Plan. In any case, a clear account of the quantity of product available and its ultimate disposition is needed to complete a recall.

The method of disposition must be documented as part of this process.

If an animal food is recalled due to a safety concern, a facility can decide to reprocess if they want to recondition the recalled animal food. The facility needs to inform FDA and State authorities and provide their reconditioning proposal, which should follow FDA Compliance Policy Guide 675.200 *Diversion of Adulterated Food to Acceptable Animal Feed Use*. This document can be found on the FDA website, www.fda.gov, under the Animal & Veterinary tab by selecting the Guidance, Compliance and Enforcement link. In addition, animal food being reworked must be handled in accordance with CGMP requirements for plant operations per 21 CFR 507.25.

The definition of *rework* "means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food."

Additional information about recalled product for industry can be found in the FDA GFI #235. The guidance on 21 CFR 507.25(a)(7) and 507.27(d)) may be particularly useful.

Effectiveness Checks

- Consignee response and follow up
- Daily reconciliation of quantity recovered versus total
 - $100 \times (\# \text{ bags recovered} / \text{total bags shipped})$
 - $100 \times (\text{tons recovered} / \text{total tons shipped} + \text{storage})$



Slide 12

The recalling establishment must determine whether its recall is progressing in a satisfactory manner. The firm has an obligation to conduct effectiveness checks as part of its recall process. These checks are used to verify that all affected customers were notified about a recall and have taken appropriate action. A Recall Plan should describe how effectiveness checks will be conducted during a recall. Most establishments follow up daily with customers via phone calls or email to ensure they are progressing in locating and segregating all affected material. In some cases, onsite assistance may be necessary at customer locations.

Some examples to evaluate the effectiveness of a recall include daily reconciliation of the volume of product recovered compared to the total quantity recalled. Calculations to quantify effectiveness may include either the number of bags or the number of tons recovered, or both.

Recall Considerations

- A recall may trigger reanalysis of the Food Safety Plan.
 - Modification of the Food Safety Plan
 - Retraining to enhance implementation effectiveness
 - Other actions to prevent recurrence of the problem
- Maintain a log of decisions made throughout recall
- After recall is completed, conduct review meeting



Slide 13

A recall suggests that a preventive control, or combination of preventive controls, or the Food Safety Plan as a whole is ineffective. If this is the case, reanalysis of the Food Safety Plan is required (507.50(b)). In some cases, modification of the Food Safety Plan may be required. For example, if a new hazard is identified, the hazard analysis should be updated to include that hazard and preventive controls should be modified or added to ensure ongoing control. In other cases, the Food Safety Plan may be adequate, but implementation of the plan may need to be improved through enhanced training, equipment upgrades or other relevant corrections. In any case, the animal food safety team should strive to determine the root cause of the problem and act quickly to take corrective actions, as appropriate.

Previous chapters described corrective actions that may be appropriate for different preventive controls, as well as the documentation requirements for corrective actions. Likewise, records of a recall should be maintained, including a log of ongoing decisions and activities, as well as a summary of the final recall review. There is a template at the end of this chapter that may be useful for a firm constructing a Recall Plan and the associated records to support these efforts.

Periodically Test the System

- Verify information in the recall plan
 - Contact information, product descriptions, templates, customer lists, supplier lists, etc.
- Test the recall team
 - Can they determine if a recall would be needed?
 - Are the right people on the team and are there alternates?
 - Do they know how to contact technical help if needed?
 - Can they trace product one-step forward and one-step back?
 - Can they create records, logs, product descriptions, press releases, etc.?



Slide 14

Once the recall plan is developed, it is important to periodically test the system to ensure that it will work if a recall is necessary. This is sometimes referred to as a “mock recall,” which is used as an industry good practice. These mock recalls typically include verifying that the information in the recall plan is current, and testing the recall team to determine if they can do what is necessary should a recall occur. Tracing products and ingredients one-step forward and one-step back in the supply chain is a common element of a mock recall; however, actual customers and suppliers are not typically contacted to avoid confusion.

Traceability checks are an important part of a mock recall. These checks determine how long it takes to identify where a specific lot of product was sent (one step forward) and to identify the source and lot code(s) of all ingredients used in the production lot (one step back). In addition, it is useful to test the recall team to see if they can determine if a recall is actually necessary, if they know who and how to contact for technical help if needed, if they can create the required documentation to perform a recall.

A test of the system can be performed over time (e.g., verifying contact information), but the importance of conducting mock recalls should not be overlooked.

Recall Plan Summary

- Recalls can involve food safety or quality issues
- Written recall plan procedures are required to:
 - Notify direct customers and distributors
 - Notify the public, when appropriate
 - Describe how to conduct effectiveness
 - Identify proper disposition of product
- Mock recalls are useful to verify that the plan is current
- Communication with FDA, state regulatory agencies, and customers is vital



Slide 15

A written Recall Plan enables rapid response to remove contaminated product from the marketplace if it contains a hazard that may cause illness or injury to humans or animals. A Recall Plan should define who to contact if a recall is necessary. Effectiveness checks are required when a recall occurs. Mock recalls are useful to ensure that the plan is current and that people understand their roles. A rapid and efficient response can reduce the number of animal and human illnesses and protect a business. Proper disposition of product is necessary, as is effective communication with FDA, state regulatory authorities, and customers.

NOTES

PUBLIC VERSION

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK—BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 5. The authority citation for 21 CFR part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. Add § 117.95 to subpart B to read as follows:

§ 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

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

PART 500—GENERAL

■ 7. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 8. Revise § 500.23 to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b) of this chapter, the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

■ 9. Add part 507 to read as follows:

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK—BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Subpart A—General Provisions

Sec.

507.1 Applicability and status.

507.3 Definitions.

507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

507.5 Exemptions.

507.7 Requirements that apply to a qualified facility.

507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

Subpart B—Current Good Manufacturing Practice

507.14 Personnel.

507.17 Plant and grounds.

507.19 Sanitation.

507.20 Water supply and plumbing.

507.22 Equipment and utensils.

507.25 Plant operations.

507.27 Holding and distribution.

507.28 Holding and distribution of human food by-products for use as animal food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

507.31 Food safety plan.

507.33 Hazard analysis.

507.34 Preventive controls.

507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).

507.38 Recall plan.

507.39 Preventive control management components.

507.40 Monitoring.

507.42 Corrective actions and corrections.

507.45 Verification.

507.47 Validation.

507.49 Verification of implementation and effectiveness.

507.50 Reanalysis.

507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

507.55 Implementation records required for this subpart.

Subpart D—Withdrawal of a Qualified Facility Exemption

507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

507.62 Issuance of an order to withdraw a qualified facility exemption.

507.65 Contents of an order to withdraw a qualified facility exemption.

507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

507.69 Procedure for submitting an appeal.

507.71 Procedure for requesting an informal hearing.

507.73 Requirements applicable to an informal hearing.

507.75 Presiding officer for an appeal and for an informal hearing.

507.77 Timeframe for issuing a decision on an appeal.

507.80 Revocation of an order to withdraw a qualified facility exemption.

507.83 Final agency action.

507.85 Reinstatement of a qualified facility exemption that was withdrawn.

Subpart E—Supply-Chain Program

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

507.110 General requirements applicable to a supply-chain program.

507.115 Responsibilities of the receiving facility.

507.120 Using approved suppliers.

507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

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

507.135 Onsite audit.

507.175 Records documenting the supply-chain program.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

507.200 Records subject to the requirements of this subpart.

507.202 General requirements applying to records.

507.206 Additional requirements applying to the food safety plan.

507.208 Requirements for record retention.

507.212 Use of existing records.

507.215 Special requirements applicable to a written assurance.

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether an animal food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Except as provided by § 507.12, if a facility is required to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term "food" in part 117 includes animal food.

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to

such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

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

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier's food safety processes and procedures.

Calendar day means every day shown on the calendar.

Correction means an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the animal food or onto surfaces that contact the animal food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and animal food-contact surfaces of equipment.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on

the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

Lot means the animal food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming,

washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (e.g., activities performed for the safe or effective packing or repacking of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public (human or animal) health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe

food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable

calendar year was less than \$500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 507.5(d).

Qualified individual means 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.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving facility means a facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

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

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged animal food means packaged animal food that is not exposed to the environment.

Validation means obtaining and evaluating scientific and technical evidence that a control measure,

combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

Water activity (a_w) means a measure of the free moisture in an animal food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

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

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 507.3, *i.e.*, have 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; and

(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.

(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.

(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

§ 507.5 Exemptions.

(a) This part does not apply to establishments, including "farms" (as defined in § 1.227 of this chapter), that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Subparts C and E of this part do not apply with respect to activities that are subject to § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at an animal food facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to those activities.

(2) The exemption in paragraph (b)(1) of this section is applicable only with respect to those microbiological hazards regulated under part 113 of this chapter.

(c) Subparts C and E of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, subparts C and E of this part do not apply to a qualified facility. Qualified facilities are subject to the requirements in § 507.7.

(e) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm packing or holding of processed animal food, and § 507.7 does not apply to on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities subject to section 418

of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations—*i.e.*, packing (or repacking) (including weighing or conveying incidental to packing or repacking); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Roughage products (*e.g.*, alfalfa meal, entire plant meal, stem meal, pomace, and pulp);

(2) Plant protein meals (*e.g.*, algae, coconut (copra), guar, and peanut);

(3) Grain by-products and processed grain products (*e.g.*, bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal);

(4) Oilseed products (*e.g.*, oil and meal of safflower, soybean, or sunflower);

(5) Molasses (*e.g.*, processed sugar cane, sugar beets, and citrus).;

(6) Animal protein meals (*e.g.*, blood, feather, meat, meat and bone, and marine (*e.g.*, crab, fish, shrimp));

(7) Milk products (*e.g.*, casein, cheese rind, and lactalbumin);

(8) Animal tissue-derived products (*e.g.*, fat);

(9) Vitamins, minerals, and concentrates;

(10) Processing aids (*e.g.*, enzymes, preservatives, and stabilizers); and

(11) Any other processed animal food that does not require time/temperature control for safety.

(f) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following low-risk manufacturing/processing activity/animal food combinations:

(1) Chopping or shredding hay;

(2) Cracking, crimping, flaking, pearling, peeling, shelling, or wafering—grain (*e.g.*, barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (*e.g.*, beans, canola, cottonseed, linseed, soybeans, and sunflowers);

(3) Crushing, dry rolling, grinding, milling, pulverizing—grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled

material, culled fruits and vegetables, roughage (*e.g.*, cobs, hulls, husks, and straws), or roughage products;

(4) Ensiling (including chopping, shredding, mixing, storing, or fermenting), that is, making silage or haylage from forage (*e.g.*, sorghum (milo), corn (maize), alfalfa, and grass), grain, culled fruits and vegetables, or roughage;

(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;

(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and

(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

(g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to any of the following:

(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(2) 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

(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) *Electronic submission.* To submit electronically, go to <http://www.fda.gov/furl> and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from <http://www.fda.gov/pcafrule>;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By December 16, 2019 for a facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified

facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if:

(1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or

(ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with § 117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food facility does not further manufacture or process the by-products intended for use as animal food.

(b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

Subpart B—Current Good Manufacturing Practice

§ 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.

§ 507.17 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 harborage for pests; and

(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

§ 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.

§ 507.20 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.

§ 507.22 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.

§ 507.25 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.

§ 507.27 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.

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as 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 human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

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

(b) One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.34(b);

(3) The written supply-chain program as required by subpart E of this part;

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the

preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

(2) The hazard analysis must be written regardless of its outcome.

(b) The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or

otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

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

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and other ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

§ 507.34 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart E of this part;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls. These include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of animal food could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to ensure that the identified hazard will be significantly minimized or prevented; and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified

hazard (except as provided in paragraph (c) of this section);

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements;

(4) You rely on your customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that your customer:

(A) Will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(B) Will only sell to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part), except as provided in paragraph (d) of this section, or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 507.37, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures

control, at a subsequent distribution step, of the hazards in the animal food product you distribute and you document the implementation of that system.

(b) You must document any circumstance specified in paragraph (a) of this section that applies to you, including:

(1) A determination in accordance with paragraph (a) of this section that the type of animal food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute.

(c) For the written assurance required by paragraph (a)(2)(ii) of this section, if your customer has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, your customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

(d) For the written assurance required by paragraph (a)(4)(ii)(B) of this section, if the entity in the distribution chain subsequent to your customer is subject to subpart C of this part and has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance that the identified hazard will be significantly minimized or prevented.

§ 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).

A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 507.38 Recall plan.

(a) For animal food with a hazard requiring a preventive control you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;

(3) Conduct effectiveness checks to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food, *e.g.*, through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.40 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system you must:

(a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c)(1) You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i);

(2)(i) Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

§ 507.42 Corrective actions and corrections.

(a) As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan or;

(B) When necessary to demonstrate the control measures can be implemented as designed:

(1) Within 90 calendar days after production of the applicable animal food first begins;

(2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so.

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.

(c) You do not need to validate:

(1) The sanitation controls in § 507.34(c)(2);

(2) The recall plan in § 507.38;

(3) The supply-chain program in subpart E of this part; and

(4) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is

not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring and verification instruments (or checking them for accuracy);

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

(ii) Records of calibration, testing (e.g., product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification

instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;

(2) Product testing as required by paragraph (a)(2) of this section.

Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1)(ii).

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the animal food;

(3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or,

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable animal food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

(a) If a facility that is solely engaged in the storage of unexposed packaged animal food stores any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged animal food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;

(4) Determination that validation is not required (§ 507.47(c)(4));

(5) Review of records (§ 507.49(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;

(7) Reanalysis of the food safety plan (§ 507.50(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;
 (vi) Environmental monitoring;
 (vii) Records review; and
 (viii) Reanalysis;
 (5) Records that document the supply-chain program; and
 (6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of a Qualified Facility Exemption

§ 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 507.62 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and E of this part on the date that is 120 calendar days after the date of receipt of the order or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85.

(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same

information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(i) The name and the title of the FDA representative who approved the order.

§ 507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

(a) If you receive an order under § 507.65 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the requirements in § 507.7.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), you may include a

written request for an informal hearing as provided in § 507.71.

§ 507.71 Procedure for requesting an informal hearing.

- (a) If you appeal the order, you:
- (1) May request an informal hearing; and
 - (2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 15 calendar days of the date of receipt of the order.
- (b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If you request an informal hearing, and FDA grants the request:

- (a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.
- (b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.
- (c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

- (1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

- (2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

- (3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

- (4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses)

whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under paragraph (c)(4) of this section are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3), and (a)(5), of this chapter, and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

- (1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

- (2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption is revoked if:

- (a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- (b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- (c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

- (1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case

of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 507.60(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

Subpart E—Supply-Chain Program

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

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

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

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement “Animal food for research or evaluation use”;

(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of; and

(iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

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

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

§ 507.110 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 507.120;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125;

(3) Conducting supplier verification activities as required by §§ 507.130 and 507.135;

(4) Documenting supplier verification activities as required by § 507.175; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 507.175, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 507.175.

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

(1) Onsite audits;

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

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

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

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

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

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

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of animal food and other FDA compliance actions related to animal food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

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

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 507.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

§ 507.115 Responsibilities of the receiving facility.

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

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

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

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

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

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any

of the following as a supplier verification activity:

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

(2) An audit conducted by its supplier;

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

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 507.110(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135.

§ 507.120 Using approved suppliers.

(a) The receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

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

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

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

§ 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

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

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

(a) Except as provided by paragraphs (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 507.110(b), as determined under § 507.110(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals:

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

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

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

(c) If a supplier is a qualified facility as defined by § 507.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 507.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens;

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interest that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity.

§ 507.135 Onsite audit.

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

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its

implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

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

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

§ 507.175 Records documenting the supply-chain program.

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

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 507.49(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification

activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities

other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable

or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

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

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 507.200 Records subject to the requirements of this subpart.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.

(b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

(d) The requirements of § 507.206 apply only to the written food safety plan.

(e) The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to the records required by § 507.7.

§ 507.202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 507.206 Additional requirements applying to the food safety plan.

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

§ 507.208 Requirements for record retention.

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the

applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.*, because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the written food safety plan (§ 507.45(b))).

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 507.212 Use of existing records.

(a) Existing records (*e.g.*, records that are kept to comply with other Federal,

State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 507.215 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:

- (1) Effective date;
- (2) Printed names and signatures of authorized officials;
- (3) The applicable assurance under:
 - (i) § 507.36(a)(2);
 - (ii) § 507.36(a)(3);
 - (iii) § 507.36(a)(4);
 - (iv) § 507.130(c)(2);
 - (v) § 507.130(d)(2); or
 - (vi) § 507.130(e)(2).

(b) A written assurance required under § 507.36(a)(2), (3) or (4) must include:

- (1) Acknowledgement that the facility that provides the written assurance

assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

■ 10. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

■ 11. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

§ 579.12 Incorporation of regulations in part 179.

* * * Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

Dated: August 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-21921 Filed 9-10-15; 8:45 am]

BILLING CODE 4164-01-P

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA LIST OF ACRONYMS

Table of Abbreviations and Acronyms	
Abbreviation/Acronym	What it means
AAFCO	Association of American Feed Control Officials
AFSS	Animal Feed Safety System
aw	Water activity
BAM	Bacteriological Analytical Method
Bioterrorism Act	Public Health Security and Bioterrorism Preparedness and Response Act of 2002
CCP	Critical Control Point.
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
Codex	Codex Alimentarius Commission
CPG	Compliance Policy Guide
CVM	Center for Veterinary Medicine
DON	Deoxynivalenol
e.g.	For example (Latin exempli gratia)
EPA	U.S. Environmental Protection Agency
EU	European Union
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FOIA	Freedom of Information Act
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture
FSIS Validation Guidelines	FSIS' Compliance Guidelines on HACCP Systems Validation
FSMA	FDA Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
FSVP	Foreign Supplier Verification Programs
GAP	Good Agricultural Practices



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA LIST OF ACRYONYMS

GFSI	Global Food Safety Initiative
GMP	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis and Critical Control Point
HHS	U.S. Department of Health and Human Services
ISO	International Organization for Standardization
LACF	Thermally processed low-acid foods packaged in hermetically sealed contain
N/A	Not Applicable
NACMCF	The National Advisory Committee on Microbiological Criteria for Foods
NIFA	National Institute of Food and Agriculture of the U.S. Department of Agriculture
OIE	World Organisation for Animal Health
OMB	Office of Management and Budget
PAS	British Standards Institute "Publically Available Specification 222:2011"
PCB	Polycarbonate biphenyls
PFP	Partnership for Food Protection
PHS	Public Health Service Act
PRA	Paperwork Reduction Act
PSA	Protein Surveillance Assignment
RA	Risk Assessment
RAC	Raw Agricultural Commodity
RFR	Reportable Food Registry
RTE	Ready-to-eat
SOP	Standard Operating Procedure
TCS	Time/Temperature Control for Safe Animal Food
USDA	U.S. Department of Agriculture

Blank Colored Insert-Front

PUBLIC VERSION

Blank Colored Insert-Back

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

EXAMPLE FOOD SAFETY PLAN DRY EXTRUDED DOG AND CAT FOOD

Owner, operator, or agent in charge: Arnold Zipfel, General Manager, ABC Pet Food 6/2/2016

This manual was created to assist participants in the Food Safety Preventive Controls Alliance's *Preventive Controls for Animal Food* course in an attempt to reinforce learning.

All examples are hypothetical. Application of preventive controls requires in-depth knowledge of actual operating conditions, thus information in the curriculum and in this example plan may not be directly applicable to a specific operation. Assistance from a *Preventive Controls Qualified Individual* is necessary to ensure compliance with FDA regulations.

Version 1.1 – 2017

Table of Contents

1. Background Information	5
Food Safety Team Members	5
Facility Overview	5
Flow Diagram	6
2. Hazard Analysis and Preventive Controls Determination	7
3. Preventive Controls and Management Components	8
Supporting SOPs	10
4. Recall Plan	11
Notification of the public	16
Notification of customers	20
Effectiveness Checks	20
Appropriate disposal of recalled animal food	21
5. Implementation Records	22
Supporting Forms	23
Locations of Records	24

PUBLIC VERSION

Example Food Safety Plan

1. Background Information

Food Safety Team Members

Name	Position
I.R. Charge*	Plant manager
F.S. Leader	Production supervisor
I.M. Quality	Quality supervisor
I.M. Fixer	Maintenance supervisor
*Preventive Controls Qualified Individual. Attended FSPCA Course for Animal Food June 2016. Completion certificate is in personnel file.	

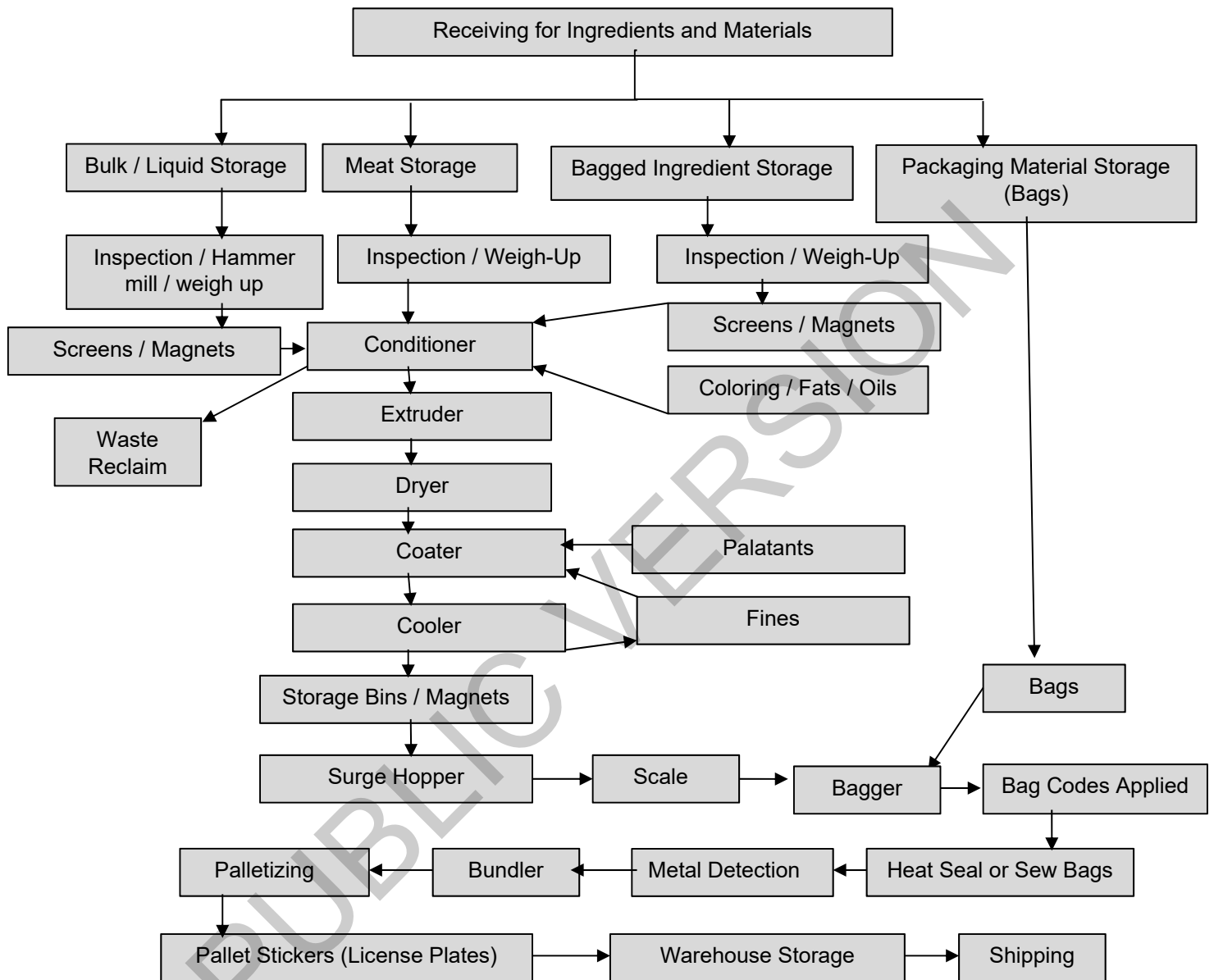
Facility Overview

- **Facility Description:** The facility was built in the 1980s and runs one shift, 5 days per week.
- **Product Description:** Complete and balanced food for all life stages of dogs and cats. Dry extruded kibble is packaged in differing bagged net weights.
- **Intended Use:** Fed as a complete ration to dogs or cats at all life stages. Fed as is, directly from the bag and stored in a cool, dry environment.

Hazard Evaluation Rubric

		Critical	Moderate	Negligible	
		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Flow Diagram



2. Hazard Analysis and Preventive Controls Determination

**Note that these sections are abridged; typical may likely require multiple pages. Additional justification may be necessary to attached, particularly for when it is determined that hazards do not require a preventive control (i.e. historical data to support thiamine levels in incoming vitamin premix are in accordance with the COA is appropriate to include).*

Table 1. Hazard Analysis							
Identification		Evaluation			Preventive Control(s)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
List Ingredients and Steps/Equipment within the Process Flow	Identify Known or Reasonably Foreseeable Hazards	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Controls Number
Ingredients	B	Salmonella spp.	I – High	Yes	FDA Salmonella CPG 690.800	Process Control: Extrusion temperature Sanitation control: Post-extruder surface sanitizing	1 2
	C	Thiamine deficiency	II- Medium	No	COA used by known supplier with historical data to confirm values	n/a	n/a
	P	Foreign material : metal, plastic, bone, glass, wood	II- Medium	Yes	Ingredients may include non-ferrous metal that may not be caught by magnet	Process Control: Metal detection in finished pet foods	3
Bulk receiving	B	Salmonella spp.	I – High	Yes	FDA Salmonella CPG 690.800	Process Control: Extrusion temperature Sanitation control: Post-extruder surface sanitizing	1 2
	C	None	n/a	n/a	n/a	n/a	n/a
	P	Foreign material : metal, plastic, glass, wood	II- Medium	Yes	Foreign material, especially metal, may enter receiving grate	Process Control: Metal detection in finished pet foods	3
Mixing	B	None	n/a	n/a	n/a	n/a	n/a
	C	Thiamine deficiency	II- Medium	No	COA used by known supplier with historical data to confirm values	n/a	n/a
	P	Metal	II- Medium	Yes	Mixer paddles made of metal	Process Control: Metal detection in finished pet foods	3

Example Food Safety Plan

3. Preventive Controls and Management Components

*Note that these sections are abridged; typical may likely require multiple pages (i.e. Preventive Control #3 is not shown).

Table 2. Description of Preventive Controls										
Preventive Control(s)					Management Components					
(1)	(2)	(3)	(4)	(5)	(6)				(7)	(8)
Hazard Requiring a Preventive Control	Appropriate Control for Hazard Requiring a Preventive Control	PC Number	PC Category	Parameters (if applicable)	Monitoring (if applicable)				Corrective Action(s) and/or Correction(s)	Records
					What	How	Frequency	Who		
Salmonella spp.	Extrusion temperature	1	Process Control	Extruder barrel temperature > 178°F (instantaneous 10 ⁶ reduction)	Automation system	Extruder records, thermometer readings	Continuous with exception alarms	Shift operator running the automation system	Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate	Extruder records, validation documents, corrective action records, and training, thermometer accuracy, thermometer calibration, and verification records
Salmonella spp.	Post-extruder surface sanitizing	2	Sanitation control	Any residual material on post-extruder surfaces or 200 ppm sanitizer concentration	Visual inspection of surfaces, sanitizer concentration	SOP 201.2	Before operations begin and end of daily production	Sanitation team member	Correction: If residual material is observed on the animal food-contact surface, re-clean and re-sanitize. If sanitizer is not at the proper concentration, make a new solution. Corrective action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate	Daily Sanitation Sheet, corrective action and correction records, training records, environmental monitoring records

**Note that these sections are abridged; typical may likely require multiple pages (i.e. Preventive Control #3 is not shown).*

Table 3. Description of Verification Activities	
Activity	Description of Activity
Type of Validation	<ul style="list-style-type: none"> Extrusion temperature <ul style="list-style-type: none"> IFT Report to FDA: Kinetics of Microbial Inactivation, 2000 AFIA <i>Salmonella</i> Control Guidelines, 2010 Bianchini et al. in 2012. Internal process data: minimum required temperature = 175.6 F Post-extruder surface sanitizing <ul style="list-style-type: none"> n/a
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	<ul style="list-style-type: none"> Extrusion temperature <ul style="list-style-type: none"> Daily checks to confirm thermometer accuracy Quarterly calibration of thermometers Test and hold procedures per SOP 506.3 Post-extruder surface sanitizing <ul style="list-style-type: none"> Environmental monitoring per SOP 213.6 Product testing when necessary per SOP 213.7
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

Recall Plan Example	PAGE 10 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Supporting SOPs

**Note that these sections are abridged; typical may likely require multiple pages (i.e. SOP 213.6, 213.7, and 506.3 are not shown, but are referenced in Tables 1, 2, or 3).*

Hazard Analysis	PRODUCT: Dry extruded dog and cat food	PAGE X of Y	Pet Food Example
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE mm/dd/yy	
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES mm/dd/yy	

SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.

Frequency: Before operations begin and at the end of daily production

Who: Sanitation team member

Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet

Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.

Corrective Action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate

Records: Daily Sanitation Sheet

Verification: Supervisor (daily) and PCQI (within 7 working days) reviews Daily Sanitation Sheet

4. Recall Plan

Reviewed by: *Signature*, Title

Date: June 2, 2016

This model Recall Plan identifies information that is either required or recommended to facilitate an effective and efficient recall. While a Recall Plan is required by the *Preventive Controls for Animal Food* regulation, no specific format and content is specified. This model contains questions and templates that can be used to develop an individualized Recall Plan. A Recall Plan must be developed as part of your Food Safety Plan records.

Recall Plan Example	PAGE 12 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Recall Team

Assignment	Person	Contact Information
Facility Manager Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Responsibility:		
Publicity and Public Relations Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Responsibility:		
Sales & Marketing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Nutritionist or Veterinarian Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Purchasing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Quality Assurance Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Accountant Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Attorney Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Administrative Support		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
FDA Recall Coordinator		Office: xxx-xxx-xxxx

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe your product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	If no recall is needed: Document why not and action.
News media story on problem with a type of animal food you produce	Assemble recall team, review internal records		If recall is needed: <ul style="list-style-type: none"> • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		

Recall Plan Example	PAGE 14 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Information Templates for FDA Communication

Product Information

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product labels
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Bag label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

Codes (Lot Identification Numbers):

- Lot number(s) involved: _____
- Lot numbers coding system: *Describe how to read your product code: -*

- Expected shelf life of product: _____

Recall Firm Contacts

Provide this information to FDA for clear communication:

Manufacturer name: [Name and address]

Position	Name, Title	Contact Information
RECALL coordinator		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Most responsible individual		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Public contact:	<i>May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator focus on retrieving product and resolving the issue</i>	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx

Recall Plan Example	PAGE 16 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Notification of the public

The public will be notified via press release using the template provided below:

***[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]
[--No Other Products Affected--]***

Contact

Consumer:

1-xxx-xxx-xxx

Media Contact:

xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- [insert lot codes]

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
---------	----------	----------

[Company Name] [insert product name(s)] [insert product codes(s)] [insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

Recall Strategy

Reason for the Recall

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (toxic metal, medication, prohibited animal protein), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL lot(s) subject to recall, or just a portion of the lot(s) subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none">• Date of complaint• Description of complaint -include details of any injury or illness• Lot Number involved	
If a State agency is involved in this recall, identify Agency and contact.	

Recall Plan Example	PAGE 18 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Volume of Recalled Product

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace	
<ul style="list-style-type: none"> distributor level customer level 	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

Distribution Pattern

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
▪ wholesalers/distributors	
▪ repackers	
▪ manufacturers	
▪ retail	
▪ consumers (internet or catalog sales)	
▪ foreign consignees (specify whether they are wholesale distributors, retailers or users)	
▪ Geographic areas of distribution, including foreign countries	

Consignee List

Commercial customers

<i>Name</i>	<i>Street Address</i>	<i>City</i>	<i>State</i>	<i>Recall contact name</i>	<i>Contact phone number</i>	<i>Recalled product was shipped?</i>	<i>Recalled product was sold?</i>	<i>Recalled product may have been shipped or sold</i>

PUBLIC VERSION

Recall Plan Example	PAGE 20 of 24	
PLANT NAME:	ISSUE DATE	08/02/2015
ADDRESS:	SUPERSEDES	05/29/2015

Level in the distribution chain

Level	Included		Rational if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Notification of customers

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

--	--	--	--	--	--	--	--

Appropriate disposal of recalled animal food

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

PUBLIC VERSION

5. Implementation Records

**Necessary components include: 1. validation, 2. verification of monitoring, 3. verification of corrective actions, 4. calibration of process monitoring equipment, 5. product testing, and 6. records review.*

In this example, the validation information that is appropriate to include is: the abstract of the IFT Report to FDA, the AFIA Salmonella Guidelines, the abstract of Bianchini et al., 2012, and the internal process data to support the minimum required temperature. For brevity, this information is not included in this example food safety plan.

Items 2 to 6 are typically included in various forms, which may or may not be part of the food safety plan. This example displays examples of supporting forms and a list of where to find the completed records, which are stored outside the food safety plan.

PUBLIC VERSION

Supporting Forms

**Note that these sections are abridged; typical may likely require multiple pages (i.e. examples of all other forms referenced in Table 2 Column 8).*

Pet Food Example				
Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y	
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy	
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy	
DATE: _____ Daily Sanitation Sheet				
Procedure	Prior to Operations ()	End ()	Comments or Corrections	Initials
Cleaning Animal Food-Contact Surfaces				
• Surface of equipment or utensil cleaned w/ squeegee				
• Surface wiped with clean cloth dipped in detergent Detergent type and strength: _____				
• Surface rinsed with clean water				
Sanitizing of Animal Food-Contact Surfaces				
• Entire surface sprayed with sanitizer Sanitizer type and strength: _____				
• Allow at least 1 minute contact time of sanitizer				
• Allow surface to air dry (apx. 5 minutes)				
• ***Inspected for residual material and cleanliness				
• ***Sanitizer concentration measured: <u>200 ppm</u>				
Supervisor signature: _____		Date: _____		
Verification of reviewer signature: _____		Date: _____		

Corrective Action Form		PAGE 1 of X
PLANT NAME: ABC Pet Food Company ADDRESS: 123 Street, Anywhere, USA		
Product Name:	Code or Lot Number:	
Date of Record:		
Date and Time of Problem:		
Description of Problem and Root Cause:		
Actions Taken to Correct the Problem:		
Person Taking Action (name and signature) :		
Amount of Product Involved in Problem:		
Evaluation of Product Involved with Problem:		
Final Disposition of Product:		
Reviewed by (Name and Signature):	Date:	

Locations of Records

Record Type	Location	Form
Training Records	Individual Personnel File, Human Resources Headquarters	Hard copy with electronic backup
Verification of Monitoring (extrusion temperature records and daily sanitation sheets)	Control room computer in file named "Daily PC Monitoring Records"	Electronic
Verification of Corrective Actions	Control room computer in file named "CA and Corrections"	Electronic
Calibration of Process Monitoring and Verification Instruments (thermometer accuracy and calibration records)	Control room computer in file named "Thermometer Records"	Electronic
Product Testing	Quality Assurance Manager Office File Cabinet	Hard copy
Records Review	Plan Manager Office File Cabinet	Hard copy with electronic backup

PUBLIC VERSION

PUBLIC VERSION