

PREVENTIVE CONTROLS FOR ANIMAL FOOD
"STANDARDIZED CURRICULUM" RECOGNIZED BY FDA

WELCOME



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* rule) can be found in Title 21 of the Code of Federal Regulations (CFR) Part 507 (21 CFR part 507), which is included as Appendix 1 in this manual. 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



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

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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*.



The 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.



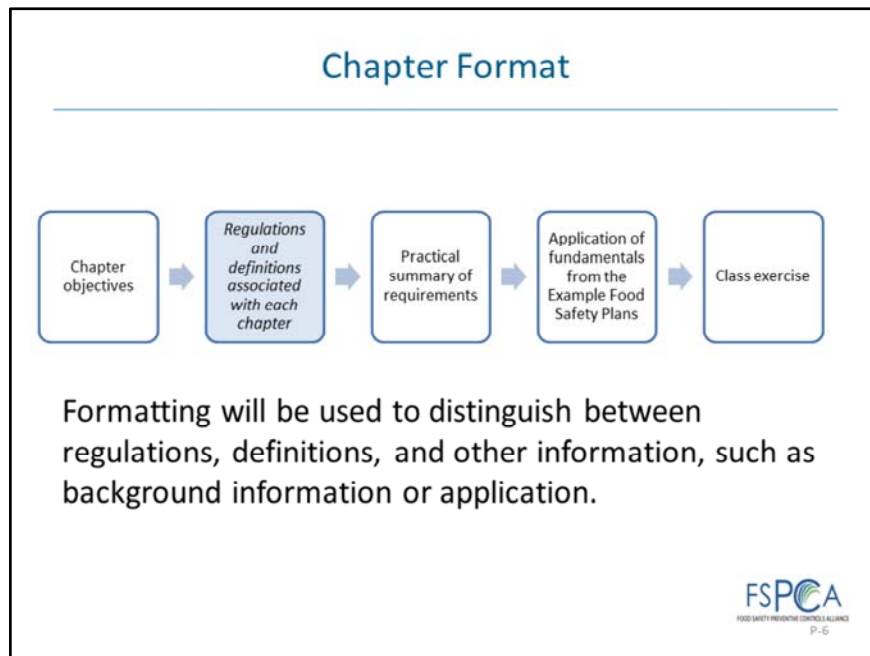
The course will help participants meet the training requirements for a *Preventive Controls Qualified Individual*. Upon successful completion of the course, you will be able to distinguish between Current Good Manufacturing Practices (CGMPs), other prerequisite programs, and preventive controls and understand 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

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.

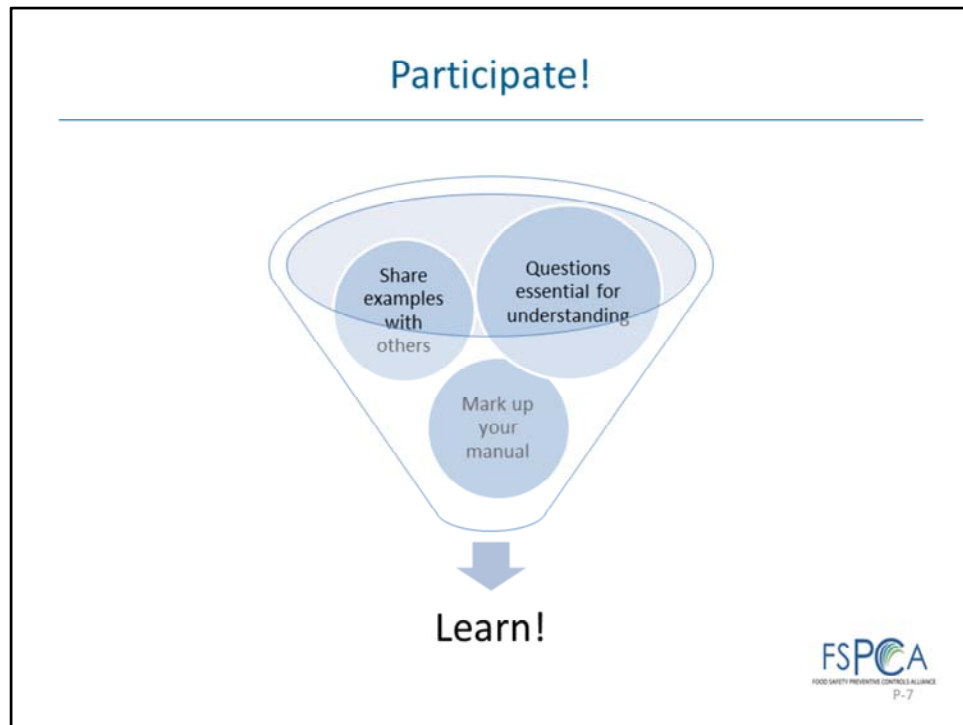


In general, the format of the individual chapters in this curriculum are divided into five parts. There are exceptions to this format, but for the most part, chapters are divided into the following five parts:

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, and a technical amendment of the rule, which largely was editorial in nature, is provided as Appendix 2. In addition, a summary of relevant acronyms is provided as Appendix 3. 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.



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	Technical Amendment
Appendix 3	Acronyms and Abbreviations Reference
Appendix 4	Example Food Safety Plan

Chapters 1 through 10 will be presented as lectures in this training, and Appendices 1 through 4 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, another appendix 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.



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 4 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 analysis, hazard control strategies, and food safety plans similar to those shown within this curriculum.
 - Other facilities may have hazard analysis 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.

As previously mentioned, the example food safety plans used throughout this curriculum and in the electronic supplements 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 visit the FSPCA website at
<http://www.iit.edu/ifsh/alliance>
for resources on preventive controls and information on
FSPCA activities.



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.