

## Module 5: Systems Approach—Regulatory Model

**Goal** Provide instructions on the major philosophical change for FSIS that demands a new enforcement strategy.

**Objectives** After completing this module, participants will be able to:

1. Explain why the Agency is changing to HACCP. **Page 2, paragraph 2**
2. Describe the HACCP concept. **Page 2, paragraph 4**
3. List industry's roles and responsibilities in the HACCP environment. **Page 5**
4. List FSIS's roles and responsibilities in the HACCP environment. **Page 5**
5. List the three types of FSIS verification described in the Regulatory Oversight Model. **Page 5**
6. Describe past inspection and future inspection. **Page 6, paragraphs 2, 3, 4**
7. Explain why the Agency is moving away from command-and-control regulations. **Page 3, paragraphs 1, 2**
8. List the skills inspection personnel must demonstrate in a HACCP environment. **Page 4, paragraph 1**
9. Describe the consequence of a system failure. **Page 7, paragraph 1**

**Steps** Introduce the video by covering the goal and objectives of this module.

For Facilitator information:

The video has been divided into two parts. Explain Part I covers objectives 1-5 and 7-8. Part II, which is shown at the end of training to summarize what has been learned, covers objectives 6 and 9.

Show the first 16 minutes of the video. Stop the video after the first paragraph on page 5 of the Script has been shown.

Go over the participant's handout.

Discuss questions 1-5 and 7-8. (Questions 6 and 9 will be discussed in Part II.)

1. Why change to HACCP?

**Answer:**

- Recent out breaks of food-borne illness
- Studies conducted by National Academy of Sciences, U.S. General Accounting Office and FSIS
- Improve food safety
- Reduce the risk of food-borne illness in the U.S.
- Make better use of the Agency's resources
- Makes industry responsible for production decisions and execution
- Will move industry and FSIS toward a more preventive approach to ensuring the safety of meat and poultry
- Eliminates confusion and clearly delineates responsibilities of FSIS and industry

The Agency feels that HACCP is the optimal framework for building science-based process control into food production systems to prevent food safety hazards.

2. What is the HACCP concept?

**Answer:**

- Systematic approach to the identification, assessment of risk and severity, and control of the microbiological, chemical, and physical hazards associated with each segment of the food system from production to consumption
- Proactive strategy that anticipates food safety hazards in a process and identifies the critical control points at which these hazards can be managed
- Emphasizes industry's role in continuous problem prevention and problem solving rather than relying on traditional facility inspections by regulatory agencies to detect loss of control
- Reflect the uniqueness of a food, its method of processing and the facility in which it is prepared

3. Define industry's role and responsibilities in the HACCP environment.

**Answer:**

- Responsible and accountable to consumers for meeting performance standards that assure the production of safe, wholesome, unadulterated, and properly labeled food products in a sanitary manner.
- Role is full responsibility for production decisions, execution, and to meet all FSIS food safety standards.

4. Define FSIS's role and responsibilities in the HACCP environment.

**Answer:**

- Responsible and accountable to consumers for the enforcement of industry performance standards that assure wholesome, unadulterated, and properly labeled meat and poultry products are being produced in a sanitary environment.
- Role is to set food safety standards, verify establishment compliance with those standards, and verify process control and pathogen reduction.

5. What are the three types of FSIS verification described in the Regulatory Oversight Model?

**Answer:**

- Basic compliance/noncompliance
- Other compliance/noncompliance
- Special {**Note:** For "Special", see Module 9b, Participant's Handout, page 2.}

6. Compare past inspection to future inspection.

**Answer:**

The HACCP Regulation represents a major philosophical change.

- In the past, inspection was primarily product specific.
- In the future, inspection will concentrate the system's approach and performance standards.
- Future inspection focuses on prevention rather than detection

7. Why is the Agency moving away from command-and-control regulations?

**Answer**

- Incompatible with HACCP and the FSIS food safety strategy
- Deprive establishments of the flexibility to innovate
- Undercut delineation of food safety responsibilities between industry and FSIS
- Conflict with the goal of reducing the risk of food-borne illness on a continuing basis
- Agency assumed responsibility for things that were the responsibility of the plant

8. What skills must inspection personnel demonstrate in a HACCP environment?

**Answer:**

Inspection personnel must continue to be critical thinkers, problem solvers, and decision-makers.

9. What is the consequence of a system failure?

**Answer:**

Immediate withholding of the mark of inspection