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

Discussion

The implementation of SSOP was the first step FSIS took toward making the change to inspection under the HACCP/Pathogen Reduction Regulation. This change, though significant, is only a portion of the change required by the regulation. As we transition to the implementation of the entire regulation, change will become a part of our daily activities. We must change the way we perform inspection to assure a safer food supply.

Recent outbreaks of foodborne illness and studies conducted over the past decade by the National Academy of Sciences, the U.S. General Accounting Office, and FSIS have established the need for fundamental change in the FSIS meat and poultry inspection program. The change is necessary to improve food safety, reduce the risk of foodborne illness in the United States and make better use of the Agency's resources. FSIS has embarked on a broad effort to bring about the necessary changes in its program. The HACCP requirement and other food safety measures were motivated by the critical need to fill a gap in the current regulation and inspection system and the lack of adequate measures to address the problem of pathogenic microorganisms on raw meat and poultry products. The Agency feels that HACCP is the optimal framework for building science-based process control into food production systems to prevent food safety hazards. HACCP also focuses FSIS inspection on the most significant hazards and controls.

The line between FSIS and industry responsibilities has often been blurred. The prescriptive nature of the existing inspection program has unintentionally caused the Agency to use a management approach to regulate the industry. This management role has led to the inspection logo becoming a government "seal of approval", which has insulated meat and poultry processors from accountability to consumers. Some establishments rely on the FSIS inspectors to do what's necessary to direct the correction of deficiencies and to ensure that outgoing products are safe, and not adulterated or misbranded. Relying on inspection personnel for food safety is problematic because the current inspection system is based primarily on organoleptic methods that can't detect the hazards of pathogenic microorganisms. The line was also blurred because of the excessive reliance of the FSIS inspection program on the detection and correction of problems after the fact, rather than assurance that problems will be prevented, systematically by design, in the first place. The changes in the HACCP/Pathogen Reduction Regulation eliminate this confusion and delineate clearly the respective responsibilities of FSIS and industry. The changes constitute a fundamental shift in the FSIS regulatory program, which FSIS is convinced will significantly enhance the effectiveness of the program and substantially reduce the risk of foodborne illness.

The Hazard Analysis Critical Control Point (HACCP) concept is a 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. In contrast to the traditional end-product inspection approach to ensuring food product safety, HACCP is a proactive strategy that anticipates food safety hazards in a process or practice and identifies the critical control points at which these hazards can be managed. A HACCP system will emphasize 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. HACCP plans reflect the uniqueness of a food, its method of processing and the facility in which it is prepared. HACCP is becoming an integral part of the safety assurance plans of food companies throughout the world, focused cost-effectively on critical control points that address issues of food safety, not food quality.

Command-and-control regulations are incompatible with HACCP and the FSIS food safety strategy, and conflict with the goal of reducing the risk of food-borne illness on a continuing basis. They deprive establishments of the flexibility to innovate, one of the primary advantages of HACCP, and undercut the clear delineation of food safety responsibilities between industry and FSIS, on which the FSIS strategy is based. FSIS has undertaken the conversion of current command-and-control regulations to performance standards. Command-and-control regulations, and the Inspection System Guide that FSIS inspectors use to enforce those regulations, resulted from the perceived need to achieve uniformity among federally inspected meat and poultry establishments. Technological advances introduce a new imperative, however. If establishments are to innovate, using new technologies to improve food safety, they can't be impeded by a one-size-fits-all regulatory system. Under contemporary conditions, affording establishments the flexibility to make establishment-specific decisions outweighs the advantages of uniformly applicable rules. Recognizing this, FSIS is changing inspection to meet the needs of the new regulatory system.

Under the command-and-control-based system, the inspector assumed responsibility for "approving" production-associated decisions. Under the new system, industry assumes full responsibility for production decisions and execution. FSIS, having set food safety standards, monitors establishments' compliance with those standards and related requirements, and under HACCP, verifies process control and pathogen reduction and control.

FSIS will reinforce its more proper regulatory oversight role and return food production management responsibilities to industry. The meat and poultry industry is 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. FSIS is responsible and accountable to consumers for the enforcement of industry performance standards that ensure wholesome, unadulterated, and properly labeled meat and poultry products are being produced in a sanitary environment.

The final rule requires federally inspected establishments to implement HACCP systems that address hazards that are reasonably likely to occur in their operations. FSIS will begin verifying HACCP system operations as part of its inspection program. FSIS has adopted HACCP as the framework for carrying out its comprehensive strategy to improve food safety. HACCP, combined with the other measures required by the regulation, will substantially improve the ability of meat and poultry establishments and FSIS to target and systematically prevent and reduce food safety hazards and, working together, to continuously improve food safety as science and technology improve.

FSIS inspection personnel are going to have to evaluate what they observe, analyze the facts (which might not be complete), decide what the performance standard is and use this information to make compliance/noncompliance determinations. Inspection personnel at the turn-of-the-century must be critical thinkers, problem solvers, and decisionmakers. Industry will be held accountable for their programs or plans through basic compliance/noncompliance, other compliance/noncompliance, and enforcement. Inspection personnel must look at processes or products and decide whether the process is in control or if there's a system failure. Inspection personnel will be required more than ever to use their knowledge, judgment, and expertise in making decisions, because the guidelines for them to follow won't be clearly defined, that is no longer black and white, but gray.

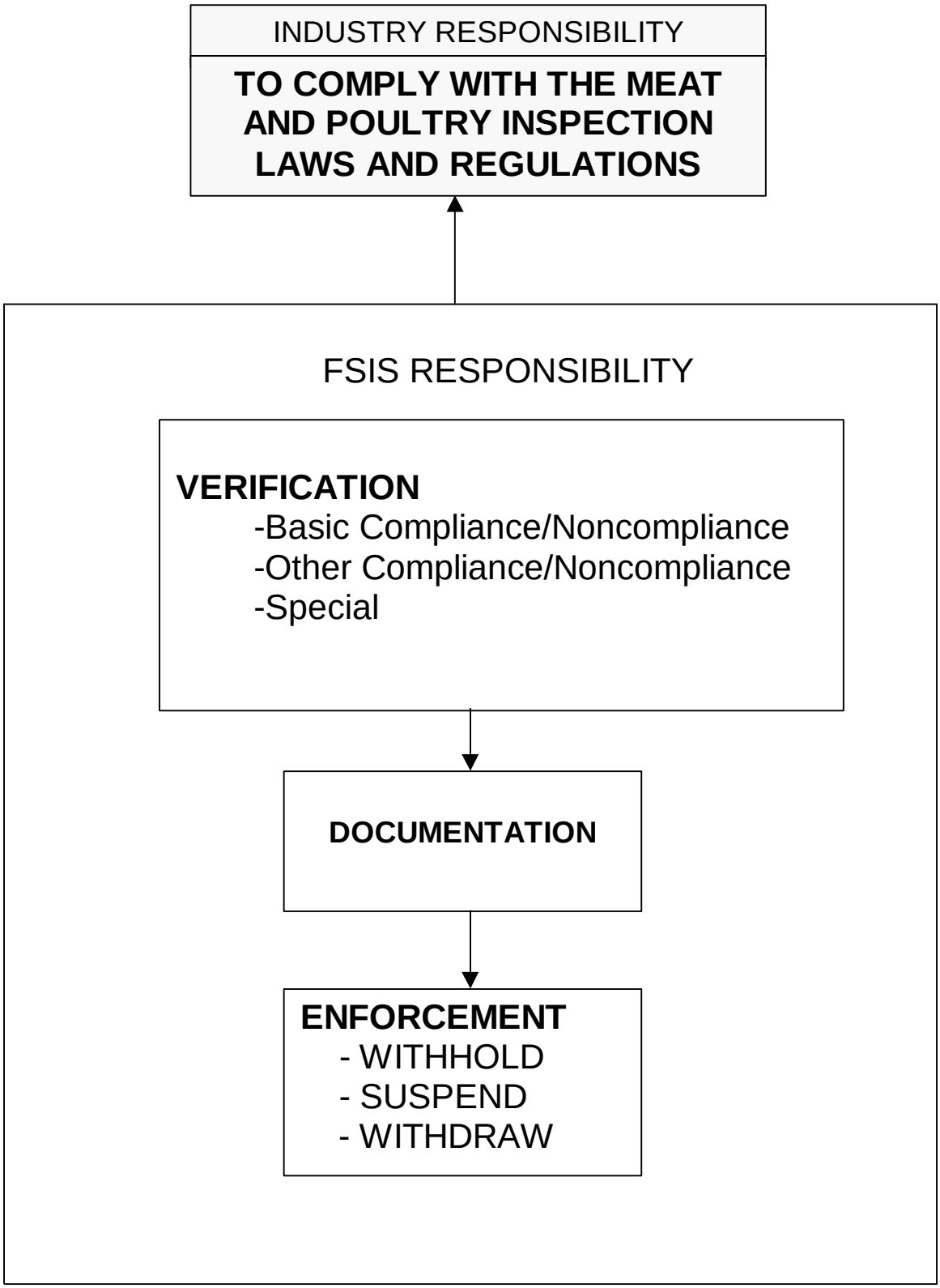
HACCP-oriented food safety inspection changes FSIS's approach to overseeing the safety of meat and poultry products. Under this new approach, FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety.

Industry will be required to establish process control systems for all forms of meat and poultry slaughter and processing and meet appropriate regulatory performance standards. By vigorous inspectional oversight of HACCP and reliance on objective test results and other observations to verify compliance with performance standards, FSIS inspection personnel will be better able to ensure that products leaving federally inspected establishments are safe. HACCP implementation will move both industry and FSIS toward a more preventive approach to ensuring the safety of meat and poultry.

The HACCP/Pathogen Reduction regulation makes it clear that industry is responsible for producing and marketing safe, unadulterated, and properly labeled and packaged products. The establishment has the responsibility for developing a HACCP plan, implementing, validating, verifying, and reassessing it.

The Regulatory Oversight Model has been used for SSOP and depicts industry agency relationships and identifies the primary focus of the new regulatory process. It will also be used for Hazard Analysis and Critical Control Points (HACCP), *E. coli* testing, and S*almonella* sampling and economic and facility requirements.

REGULATORY OVERSIGHT MODEL



The establishment must comply with all regulatory requirements. The establishment must develop written plans/procedures for HACCP, SSOP, and *E. coli*. Under the "basic" component of FSIS's verification portion of the Regulatory Oversight Model, inspection personnel will verify that the plan/procedures meet regulatory requirements. Under the "other" component of FSIS's verification portion of the Regulatory Oversight Model, inspection personnel will verify that the establishment has properly implemented the plan or procedure and met other regulatory requirements, for example, *Salmonella* performance standards, facilities, equipment, product wholesomeness, product standards, and labeling. Any time inspection personnel determine that regulatory requirements haven't been met, the noncompliance will be documented and appropriate enforcement action will be taken. Upon initiation, inspection personnel verify that the plan or procedure contains all regulatory requirements. If the regulatory requirements aren't included in the plan or procedure, the nonconformance is documented and enforcement action is taken. Additional verification activities and noncompliance documentation are used to determine if there has been a system failure. Enforcement is the action taken by inspection personnel when a failure has occurred.

The HACCP Regulation represents a major philosophical change for FSIS and demands a new enforcement strategy. Under traditional inspection, the finding that product is not adulterated is based on FSIS inspectors examining the product. Under the new regulatory framework, the finding that product is not adulterated is based on FSIS concluding that the establishment's food safety and sanitation control systems are preventing adulteration. It provides a clear distinction that industry is fully responsible for the compliance of the products it produces and markets.

The traditional system bases enforcement actions on the concept that inspection personnel document deficiencies and establishments correct them. When inspection personnel have documented repeated failures pertaining to plant performance and plant management has failed to act effectively to prevent those deficiencies from recurring, the IIC, in conjunction with the circuit supervisor, make the decision that the plant is placed under Progressive Enforcement Action (PEA). These failures involve deviations or deficiencies, in-plant performance, and plant management's inability or unwillingness to act to effectively prevent recurrences.

The new system, however, focuses on prevention, rather than detection, of problems. As long as establishments maintain their control systems properly—including detecting, documenting, and correcting unavoidable deficiencies—FSIS will not need to take enforcement action. Many of these establishments will use the Statistical Process Control (SPC) concept that includes the notion of normal variation. Any process or step in a process has variation, including the FSIS regulatory decision-making process. The question is, is the variation normal and expected? Thus, it is very important to know what variation is normal, because action can be taken to avoid pointless attempts to correct problems that do not exist.

Under the new prevention-oriented system, when a plant finds deficiencies, it means that its control systems are working. It is when problems are not detected, or not corrected, or the same problems keep occurring, that there is reason for concern. When noncompliance findings are discovered in this environment, inspection personnel will have to analyze many different aspects of the process or system before initiating enforcement actions. Enforcement actions are different for isolated noncompliance findings than for noncompliance findings that constitute system failures. Inspection personnel will have to use their knowledge, judgment, and all available information when making this determination. Since withholding actions will be taken when there is a system failure, it is imperative for inspection personnel to have the ability analyze situations and choose just or wise actions based on the circumstances presented.

Withholding action will be enforced if the IIC has documented that a HACCP system did not prevent the production or distribution of adulterated product. Withholding action should also be enforced if the violations include failures to comply with requirements for monitoring of CCPs, to respond to deviations from critical limits, and to document verification and review of production records. In these cases, FSIS inspection personnel will not allow products to be marked “inspected and passed”.

The FSIS workforce will be better trained and equipped to focus on its primary role of ensuring compliance with the statutes and regulations. In the past we have focused primarily on inspecting products to sort out unsuitable meat and poultry. In the future, inspectors, aided by compliance officers, will concentrate on documenting breakdowns in required controls and other violations that could subject firms and individuals to enforcement

As a review of the material covered in this module, the facilitator will cover the following points with you.

1. Why change to HACCP?

2. What is the HACCP concept?

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

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

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

6. Compare past inspection to future inspection.

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

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

9. What is the consequence of a system failure?