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HACCP AND MEAT AND POULTRY INSPECTION

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Good morning. My name is John McCutcheon, and I am the Associate Deputy Administrator of Field Operations, of the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture. FSIS is the federal Agency responsible for ensuring the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products.

It's a pleasure for me to be here today. I've been asked to tell you about the Hazard Analysis and Critical Control Point, or HACCP system, as it relates to meat and poultry inspection.

This is an exciting time for us.

Before doing so, however, I'd like to take a few moments to describe recent developments in the Administration's Food Safety Initiative.

FSIS operates under the authority of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS sets standards for food safety and inspects meat, poultry, and egg products produced domestically and imported. Our mission is to protect the public health and safety.

Recently, we have broadened our food safety strategy to cover the entire farm-to-table continuum. Much of the support for our efforts has come from the White House, under President Clinton's Food Safety Initiative. The initiative focuses on six major areas: 1) the development of a nationwide early-warning system for foodborne illness; 2) improvement in risk-assessment capabilities through an interagency consortium, that will coordinate and guide overarching Federal risk assessment research related to food safety; 3) development of new research methods to detect the presence of pathogens in food, enhance our understanding of how pathogens become resistant to food-preservation techniques and antibiotics, and develop new technologies for the prevention and control of pathogens; 4) improvement of inspection and compliance by agencies responsible for food safety, including greater use of HACCP; 5) development of a public-private partnership to develop and encourage dissemination of standard food safety messages; and 6) initiation of long-range strategic planning to address public health, resource and management questions facing Federal food safety agencies.

The President directed the USDA, Health and Human Services (HHS), and the Environmental Protection Agency (EPA) to consult with all interested parties to identify and report on specific steps to improve the safety of the food supply, and to ensure it remains the safest in the world. Two public meetings were held to solicit input from States, consumers, producers, industry, universities, and the public. The final report, released May 12, 1997, reflects the interactive process. It outlines steps USDA, HHS, and EPA will take to reduce foodborne illness.

These more recent developments build on our earlier efforts in this arena that have already come to fruition with the publication of our landmark rule on Pathogen Reduction and HACCP Systems, on July 25, 1996. This rule is the centerpiece of our new regulatory approach and will enable us to step confidently into the 21st century. The rule mandates HACCP, sets certain food safety performance standards, establishes testing programs to ensure that standards are met, and assigns new tasks to inspectors to enable them to ensure regulatory performance standards are met. The final rule applies to 6,500 federally inspected and 2,550 state inspected slaughter and processing plants in the U.S., as well as to countries who export meat and poultry products to the U.S. Although egg products are not covered by the rule, yet, we have developed a strategy, including HACCP, to improve the safety of eggs and egg products. We'll extend this system to cover eggs, eventually.

What is HACCP? HACCP is a process control system designed to enable industry to identify and prevent microbial, chemical, and physical hazards in food production, and correct deviations as soon as they're detected. It is based on the premise that the logical and proven way to ensure safe food and prevent problems is to control the process from beginning to end, rather than detecting problems at the end of the line. HACCP is comprised of 7 steps: 1) Hazard analysis; 2) Critical Control Points; 3) Establishment of Critical Limits; 4) Monitoring Procedures; 5) Corrective Actions; 6) Record Keeping; and 7) Verification Procedures.

Under the new rule, businesses that produce food are accountable for its safety. They need to maintain control over their systems for sanitation, sanitary dressing, and food processing. They need to ensure their systems include established procedures to prevent, eliminate, or reduce to an acceptable level hazards that may occur. To accomplish this, all plants must develop and implement a HACCP plan for each process, and conform to the principles of HACCP.

This is not a "one-size-fits-all" approach. Rather, each plant designs its own plan to meet USDA regulatory requirements. Each plan must be transparent and self-contained. The plans are required to address those Critical Control Points (CCP's) that affect product safety as opposed to those related to economic adulteration, labeling, or quality concerns. Other inspection measures remain in place to address those areas. This is regulatory

reinvention in action.

HACCP implementation is occurring in phases, to take into account plant size. The largest plants, those with 500 or more employees, were required to have HACCP systems in place by January 26, 1998. These plants account for about 75% of slaughter production and 50% of processed product production. Small plants, those with 10 or more employees but fewer than 500 employees, are required to implement HACCP by January 25, 1999. Very small plants, those with fewer than 10 employees or annual sales of less than \$2.5 million, are required to implement HACCP by January 25, 2000.

As of February 4, 1998, HACCP has been implemented in 297 large plants throughout the U.S. Over 2000 inplant (FO) personnel have undergone extensive HACCP training. Based on reports from across the country, the training has been extremely effective, and has enabled inspectors and supervisors to carry out their oversight responsibilities with even greater detail and scrutiny than in the past. Inspectors are verifying that HACCP plans conform with regulations, verifying how the plants are carrying out their hazard prevention and sanitation responsibilities, documenting failure to meet regulatory requirements, and enforcing regulations when a plant is not in conformance with regulatory requirements.

Prior to conducting any verification activities, FSIS inspectors participate in a plant awareness procedure. FSIS initiated this procedure, whereby inspection personnel meet with plant management and develop a working understanding of each plant's HACCP plan. This plant awareness procedure has facilitated communication between plant management and inspection personnel concerning how the HACCP system was designed to function in each facility. When questions have arisen, our Technical Service Center in Omaha, Nebraska has played a strategic role in support of FSIS personnel.

USDA inspectors will continue to be present every day in plants, to verify a plant's compliance with its HACCP plan, and take direct action when necessary. Our inspectors have lost no authority on the production line. They continue to have authority to take action to ensure that establishment HACCP systems can produce product that meets food safety regulations, and to assure that affected product is disposed of properly.

Enforcement

As a logical nexus, the changing roles of the regulated industry and inspection have stimulated changes in the compliance functions of FSIS. The conceptual shift from government to industry and overall pro-active approach to food safety and process evaluation has enhanced the importance of an effective enforcement program. Our new inspection system has been strengthened by integrating the work of our inspectors with our Compliance

Staff. This enables FSIS to use a team approach to plant enforcement actions and to respond quickly to situations, to determine whether corrections have been effective.

When HACCP or sanitation system failures occur, compliance officers assist inspectors by reviewing documentation of failures of plant control systems and help ensure appropriate due process when enforcement actions are needed. This includes suspending the use of inspection marks, suspending or withdrawing inspection, or holding suspensions in abeyance, and closing plants.

While Pathogen Reduction and HACCP regulations provide the industry with enormous flexibility to develop and implement innovative measures for producing safe foods, they also impose clear and unequivocal responsibilities for preventing contamination by pathogens and other hazardous substances. Industry is accountable for food safety. This means that inspectors and compliance officers must now verify industry practices and take enforcement actions when a plant's control systems fails to meet regulatory requirements.

Essentially, with HACCP, FSIS has linked a plant's ability to control processes and the eligibility of their products to bear the marks of inspection. If a plant cannot demonstrate the effectiveness of its system, a withholding action will be issued, which could lead to a formal action to withdraw inspection, permanently.

We are committed to a systematic process to ensure safe food for consumers. HACCP provides us with tools to stop operations where there is a pattern of repetitive deficiencies, and insist on preventive measures to improve food safety before a plant can reopen. Meat and poultry plants must therefore continually and consistently demonstrate to FSIS inspectors that product is not adulterated, and that plant sanitation and process control systems prevent adulteration. They must also demonstrate truthful and accurate record-keeping. They need to verify that their control measures have worked, and that their products are safe and wholesome.

Where We're Going: Inspection Reform

Although we have made significant progress with HACCP and other aspects of the Pathogen Reduction rule, we are committed to continuing to improve our traditional inspection program for meat and poultry, and continuing to address other areas of food safety in the farm-to-table continuum. Changes in inspection methods and focus will benefit us all. However, the PR/HACCP rule is not the end of the line; there's still a lot for us to do. I'd like to now share some of our new initiatives with you.

First, we plan on continuing to improve our inspection system through

experimentation with new models for in-plant slaughter inspection. These models will provide the same level of protection, but allow some inspection resources to be reallocated to food safety tasks off-line in slaughter plants, to new food safety tasks in processing plants, and during the distribution of meat and poultry products once they leave the plant.

The HACCP-based Inspection Models Project will describe for slaughter and slaughter processing plants that have implemented HACCP, what alternative inspection models FSIS could use that would enhance food safety accountability and maintain the other consumer protection accomplishments of the present system. Today, plants must develop HACCP systems around our ante and post mortem inspection stations. Plants participating in this project will be able to develop HACCP through all aspects of the production system, including those presently constrained by our inspection activities. In other words, we would still perform carcass-by-carcass examinations, but how we do the examinations may differ.

Second, we are interested in systematically focusing on conditions and practices during distribution that may contribute to the growth of pathogens. "In-distribution" aspects of food safety include transportation, out-of-plant locations, storage, commercial kitchens, retail stores, restaurants, hotels, and other institutions. These are vital links in the farm-to-table food safety continuum. With regard to transportation and storage of meat and poultry products after they leave the FSIS inspected plant, we believe the federal government has a responsibility to set standards regarding such inspection matters, and we have been working with FDA on this issue.

Regulatory requirements for in-distribution food safety may focus on meeting time and temperature requirements. These, combined with in-plant regulatory requirements for zero fecal contamination, form the foundation of a system that produces safe and wholesome food. We are currently examining the relationship between in-plant and in-distribution regulatory requirements and enforcement locations, to see how we can most efficiently and effectively redeploy our resources from areas of other consumer protection, to focus on food safety, ensure standards are met, and to assure that the public gets the maximum return from its investment in food safety.

Third, we are concerned that small and very small companies that are scheduled to implement HACCP in 1999 and 2000 have the necessary technical guidance to help them prepare for implementation. As part of our Small Plant Demonstration Project, we have recently announced the availability of thirteen generic HACCP models to serve as guides in developing plant-specific HACCP plans at the lowest possible cost. These models are roadmaps for developing HACCP plans.

In addition, we're in the process of revising two publications: "Guidebook for

Preparation of HACCP Plans," and the "Meat and Poultry Products Hazards and Control Guide." These two publications were reissued for public comment, along with HACCP Model Plans. The public comment period has closed and we're in the process of considering the comments prior to revision.

And finally, fourth, we are looking at passing new regulations. For example, we published our "Proposed Rules of Practice" in the Federal Register, just last month. (January 12, 1998) These proposed rules are intended to supplement existing rules of practice, but clarify the responsibilities of a plant regarding refusal, suspension, or withdrawal of inspection services when the Agency determines that a plant's HACCP systems are inadequate or ineffective, or a plant is not meeting other regulatory requirements associated with the PR/HACCP rule. In addition, the Clinton Administration has asked Congress for authority to fine companies for violations of food safety standards.

Conclusion:

In conclusion, inspectors will become more important in the FSIS of the future, albeit their jobs will most likely differ somewhat from what they perform today. The cooperative relationships we're forging with other federal agencies, state and local governments, consumers, and the industry, in addition to the new roles our inspectors are playing, we believe, will lead to a safer food supply. Accountability and responsibility are key in these efforts.

These philosophies extend beyond our domestic borders. Any government exporting meat and poultry products to the United States will be required to meet our standards. A foreign country must demonstrate the equivalency of its inspection program before its products will be allowed into the U.S.

HACCP provides a logical and science-based framework for a food safety regulatory system in which inspection, enforcement, and technological resources are targeted to the most significant food safety hazards. In conjunction with regulatory reform and reorganization to deploy available resources efficiently and effectively, HACCP presents us with a "win-win" situation. For consumers, HACCP implementation means safer food and less foodborne illness. For animal producers, HACCP implementation provides you with new opportunities to provide cleaner and safer livestock and poultry to the food processing sector. Finally, for regulated industry, HACCP implementation means you have the opportunity to prove your commitment to and accountability for providing the safest food in the world.

We know there is no silver bullet that guarantees food safety, and that consumers must remain vigilant and continue to follow safe meat and poultry handling labels and practices. However, this new system is a victory for

American consumers, and we at FSIS are committed to making HACCP work.