

FOOD SAFETY AND INSPECTION SERVICE

Submitted for the Record

**Statement of Dr. Merle Pierson, Deputy Under Secretary for Food Safety
Before the Subcommittee on Civil Service and Agency Organization**

Madame Chairwoman and Members of the Subcommittee, I appreciate the opportunity to speak with you about the important issue of protecting the nation's food supply. I am Dr. Merle Pierson, Deputy Under Secretary for Food Safety at the U.S. Department of Agriculture (USDA). I also am pleased to be here today with Dr. Robert Brackett, my colleague from the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), whom I've had numerous opportunities to work with on issues of mutual concern. I would also like to thank the General Accounting Office (GAO) for its efforts to provide a better understanding of our nation's current food safety system and structure. GAO's research has provided valuable information and has helped facilitate open discussions about our current system.

I applaud your interest in the safety and security of the U.S. food supply and look forward to a full discussion on the issues you are raising today. Over the years, there has been much discussion about consolidating all food safety, inspection, and labeling functions into one Agency with the intention of increasing the effectiveness of the food safety system. In 2002, the White House established a Policy Coordinating Committee (PCC), led by the Domestic Policy Council and the National Economic Council, to look into the single food agency issue. The PCC concluded that the goals of the Administration are better advanced through enhanced

interagency coordination rather than through the development of legislation to create a single food agency.

In my testimony, I will discuss components of an effective food safety and security system, USDA Food Safety and Inspection Service's (FSIS) role in the U.S. food safety and security system, the success of U.S. food safety and security efforts, and our cooperative efforts with our food safety partners. Because we understand and recognize the rationale of some stakeholders who believe that the existing food safety system is confusing, I will also raise important issues that should be considered before making changes to our Nation's current food safety and security system. However, in our view, the most important question is whether the various Federal agencies with food safety authorities are working together effectively to address food safety and security. I believe the existing system is working. The American food supply continues to be among the safest in the world.

Building a Risk- and Science-Based Food Safety and Security System

Any food safety and security system must be able to meet current and future food safety and security challenges. In addition, I strongly believe that any effective food safety and security system must be rooted in public health and security.

FSIS believes – and both GAO and the National Academy of Sciences agree – that a critical component of an effective public health food safety and security system is the use of a verifiable inspection system that is both risk-based and science-based. A risk-based system is based on the premise that the most effective and efficient method of allocating resources is to base them on

the assessment of greatest risks/hazards. A science-based system builds upon a risk-based system, by ensuring that the risks/hazards are taken into account to develop science-based programs and policies. A verifiable inspection system based upon these two premises provides assurance that the system is meeting its public health goals.

FSIS' Role in the Food Safety and Security System

FSIS has a long, proud history of protecting public health, dating back to 1906. FSIS' mission is to ensure that meat, poultry, and egg products prepared for use as human food are safe, secure, wholesome, and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), and the regulations that implement these laws. FSIS has jurisdiction over products that generate more than \$120 billion in sales, which represents one-third of all consumer spending on food. This is an enormous responsibility and one we take very seriously.

Ensuring the safety of meat, poultry, and egg products requires a strong infrastructure. To accomplish this task, FSIS has a large workforce of approximately 10,000 employees, mostly stationed in the field on the front lines and dedicated to rigorous inspection. In fiscal year (FY) 2003, over 7,600 inspection personnel were stationed in about 6,000 federally inspected meat, poultry, and egg products plants every day that they were in operation, verifying that the processing of 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, and 3.7 billion pounds of liquid egg products complied with statutory requirements. In addition to domestic products, 3.8 billion pounds of imported meat, poultry, and processed egg products were

presented for entry into the U.S. from 28 of 33 countries eligible to export to the United States in FY 2003. Assuring that these products are safe and wholesome is a serious responsibility.

On the international front, FSIS actively participates in the development of international food safety standards through the Codex Alimentarius Commission. As the highest ranking food safety official in the United States, the Under Secretary for Food Safety at the USDA leads the U.S. Codex Office. The U.S. Codex Office is located within the Food Safety and Inspection Service.

FSIS' Inspection System

FSIS currently operates under a science-based system. Science allows for policy decisions to be continually updated based on technological advances and to respond to emerging threats. Science-based decision-making is objective and preventive in nature, and thus, it offers the best foundation for the development of policies that will achieve the desired result of improving public health, both in the short term and the long term. Threats to public health – both intentional and unintentional – need to be understood and addressed within the context of the best available research and risk analysis. With input from the scientific community, FSIS can develop practical policies that allow the industry to implement new technologies as food safety interventions.

Thanks in part to the efforts by FSIS to follow this scientific approach in administering its food safety programs, the American public remains confident in the safety of the U.S. food supply. Our efforts are paying off, as seen by the decline in foodborne illness over the last six years. The Centers for Disease Control and Prevention (CDC) attributes these results in part to the

implementation of the Hazard Analysis Critical Control Point (HACCP) system in all meat and poultry plants in the United States.

In addition, FSIS has seen a dramatic decline in pathogen levels in regulatory samples. Late last year, the agency released data that showed a 25 percent drop in the percentage of positive *Listeria monocytogenes* samples from the previous year, and a 70 percent decline compared with years prior to the implementation of the HACCP program. In June 2003, to further reduce the incidence of *Listeria monocytogenes*, we issued regulations for establishments producing ready-to-eat products.

Our measures to prevent *E. coli* O157:H7 contamination of ground beef have yielded similar results. In September 2002, based on evidence that *E. coli* O157:H7 is a hazard reasonably likely to occur at all stages of handling raw beef products, FSIS issued a directive requiring all establishments that produce raw beef products to reassess their HACCP plans. Last year, FSIS' scientifically trained personnel conducted the first-ever comprehensive audits of more than 1,000 beef establishments' HACCP plans. A majority of those plants made major improvements based on their reassessments, and, as a result, we are seeing a substantial drop in the percentage of ground beef samples that are positive for *E. coli* O157:H7. In 2003, of the ground beef samples collected and analyzed for *E. coli* O157:H7, only 0.30 percent tested positive, compared to 0.78 percent in 2002 – a 62 percent reduction. This is a definite and dramatic improvement, and the strongest signal that science can drive down the threat from pathogens.

However, the emergence of previously unrecognized pathogens, as well as new trends in food distribution and consumption, highlights our need for new strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry and egg products. To improve the application of risk analysis to regulatory and enforcement activities, FSIS is exploring the development of a real-time measure of how well an establishment controls the biological, chemical, and physical hazards inherent in its operations. Such a predictive model would help the agency make better resource allocations across the country's approximately 6,000 meat and poultry establishments to maximize food safety and public health protection.

FSIS Authorities

FSIS currently operates under appropriate legal and statutory authorities – namely the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Under the authority of these Acts, FSIS provides continuous inspection of all meat, poultry, and egg products prepared for distribution in commerce and re-inspects imported products, to ensure that they meet U.S. food safety standards.

FSIS has many regulatory responsibilities in addition to these inspection activities. The Agency sets requirements for meat and poultry labels and for certain slaughter and processing activities, such as plant sanitation and thermal processing, that the industry must meet. FSIS tests for microbiological, chemical, and other types of contamination and conducts epidemiological investigations in cooperation with the CDC based on reports of foodborne health hazards and disease outbreaks. In addition, the Agency conducts enforcement activities to address situations where unsafe, unwholesome, or inaccurately labeled products have been produced or marketed.

Meat, poultry, and egg products imported into the United States must be produced under processes equivalent to those applied to U.S. domestic establishments to ensure that they attain the same level of wholesomeness and safety and are accurately labeled. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls, which includes audits of a country's foreign inspection system and port-of-entry reinspection. FSIS reinspects imported meat and poultry products entering the United States to verify that a country's inspection system is working. FSIS import inspectors ensure that each shipment of meat and poultry products is properly certified, examine each lot for general condition and labeling, and conduct reinspection based on the agency's risk-based systems approach to sampling. In addition, FSIS annually reviews inspection systems in all foreign countries eligible to export meat and poultry to the United States to ensure that they are equivalent to those under U.S. laws. During foreign reviews conducted in FY 2003, FSIS audited 340 plants and delisted 25 of those plants after finding that their individual system of inspection and controls was ineffective.

FSIS is also responsible for assessing whether State inspection programs that regulate meat and poultry products are at least equal to the Federal program. The 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act established the "at least equal" standard. Products produced under the State programs may be distributed only within the State in which they were produced. FSIS assumes responsibility for inspection if a State chooses to end its inspection program or cannot maintain the equivalent standard.

Additionally, the 1967 Wholesome Meat Act extended FSIS jurisdiction over meat and meat products beyond the plant, granting authority to regulate transporters, renderers, cold storage warehouses, and animal-food manufacturers. As a result of this action, FSIS also has responsibility to ensure, during all points of distribution, that meat and meat food products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS uses program investigators throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Every year, on average, FSIS program investigators conduct approximately 11,000 compliance reviews, detain approximately 13 million pounds of suspected products and issue more than 1300 letters of warning. As a result, FSIS suspends operations at more than 100 plants and refers approximately 30 cases for criminal prosecution to the Department of Justice annually.

Food Security

While the events of September 11, 2001, brought the issue of the vulnerability of our food supply to the forefront, FSIS' food biosecurity efforts did not start on September 12, 2001. FSIS' century worth of experience in dealing with food emergencies has allowed the agency to develop the expertise to protect the U.S. meat, poultry, and egg products supply wherever and whenever emergencies or new threats arise. However, FSIS cannot carry out these efforts alone. Instead, FSIS works closely with the White House Homeland Security Council, the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), the USDA Homeland Security Staff, and other Federal, State and local partners to develop and carry out strategies to protect the food supply from an intentional attack.

As a result of partnering with our Federal, State, and local food safety partners, the agency has strengthened existing efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism. For example, FSIS, along with HHS-FDA and industry partners, is working with DHS to establish a new food information sharing and analysis activity for the food sector. This public/private partnership will aid in the protection of the critical food infrastructure by centralizing the information about threats, incidents, and vulnerabilities.

In addition, the President's recently signed Homeland Security Presidential Directive 9 has been in development since late 2003 and has served as a source of interagency cooperation resulting in even stronger working relationships among food regulatory agencies. The new Directive recognizes and addresses the need for interagency cooperation and communication to address food defense issues by establishing joint leadership as the goal to secure the Nation's agriculture production and food supply from terrorist attacks, major disasters, and other emergencies. This new Presidential Directive, coordinated by DHS, promotes interagency leadership by establishing a national policy on agriculture and food defense. The goal of this Directive is to harness the collective problem solving and resource amplification of a multiagency effort to better protect the Nation's food supply.

To further refine the nation's ability to respond to an attack on the food supply, FSIS also works with its food safety and law enforcement partners to conduct food security exercises. These exercises give agency employees the opportunity to simulate their actions in response to a threat on the food supply and have allowed the agency to recognize and correct vulnerabilities in its

Homeland Security response plans. In addition, FSIS has conducted its own vulnerability assessments of regulated domestic and imported products. The assessments identify potentially vulnerable products and processes, likely threat agents, and points along the production/consumption continuum where attack is most likely to occur. Using this information, the agency will focus its resources on the points of greatest vulnerability.

FSIS also works with its partners to protect the food supply through our import reinspection activities. To further strengthen our import inspection program, we established a new position called the import surveillance liaison inspector, using funds provided in the FY 2001 Homeland Security Supplemental Appropriations Act. These inspectors augment the current activities of traditional FSIS import inspectors at locations across the country. The import surveillance liaison inspectors conduct a broader range of surveillance activities, and they coordinate with other agencies, such as the Animal and Plant Health Inspection Service (APHIS), HHS-FDA, and the U.S. Customs and Border Protection within the DHS. Currently, 20 of these new inspectors are on board, and we anticipate more will be added as the need arises.

Another example of coordination with our partners is the Food Emergency Response Network (FERN) initiative. A nationwide laboratory system with sufficient capacity to meet the needs of anticipated emergencies is integral to any bioterror surveillance and monitoring system. FERN consists of Federal and State governmental laboratories which are responsible for protecting citizens and the food supply from intentional acts of biological, chemical, and radiological terrorism. Currently, over 60 laboratories, including public health and veterinary diagnostic laboratories, representing 27 States and five Federal agencies, have agreed to participate in

FERN. The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that FSIS could call upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the meat, poultry, or egg supply.

Because everyone has a stake in a safe and secure food supply, FSIS has worked closely with HHS-FDA and other public health agencies to provide food security guidelines to businesses engaged in the production and distribution of food products during transportation, distribution, and storage. These guidelines provide safety measures to prevent physical, chemical, or microbiological contamination of food products during transportation and storage, including measures that deal specifically with the prevention of intentional contamination due to criminal or terrorist acts. This publication is just one in a series of food security guidelines issued by FSIS that includes *FSIS Security Guidelines for Food Processors* and *Food Safety and Food Security: What Consumers Need to Know*, as part of the agency's continuing effort to protect public health by preventing and responding to contamination of the food supply throughout the farm-to-table continuum.

Coordination and Cooperation with Our Food Safety Partners

FSIS routinely communicates and coordinates with other government entities to ensure a safe and secure food supply. With authority over meat, poultry, and egg products, FSIS plays an integral role in ensuring the safety of America's food supply. As a partner in the U.S. food safety effort, FSIS strives to maintain a strong working relationship with its sister public health agencies. Cooperation, communication, and coordination are absolutely essential to effectively address public health issues. I'd like to discuss just a few of the many examples of situations in

which FSIS has successfully partnered with other public health agencies to solve food safety issues and crises.

BSE Coordination

The December 2003 discovery of a single case of Bovine Spongiform Encephalopathy (BSE) in Washington State provides an excellent example of the strong communication ties and the cooperation between USDA and its Federal and State food safety partners. The Federal government's swift and substantial reaction to the BSE diagnosis played a vital role in maintaining high consumer confidence. FSIS and its sister agencies moved effectively and forcefully upon the discovery of a BSE case in this country, further strengthening already formidable BSE preventive measures. Being a part of the continuous briefings, planning meetings, international trade discussions, and all the other events surrounding this situation has helped ensure that the Federal government has been speaking with one voice on this issue and that food safety and security remain a central component of our actions. FSIS has worked closely with APHIS and other mission areas in USDA, FDA, State and local governments, industry, and consumers to ensure our BSE prevention and response measures are fully effective in the United States.

MOU with FDA

Since 1999, FSIS and FDA have had a Memorandum of Understanding (MOU) to exchange information on an on-going basis about establishments that fall under both jurisdictions. FSIS will continue to collaborate and partner with FDA and other agencies who share public health and food safety responsibilities. The Bioterrorism Act of 2001 (P.L. 107-188) further enhanced

this cooperation by authorizing FDA to commission FSIS employees to conduct inspection at dual jurisdiction facilities.

Public Health Service Commissioned Corps Officers

In addition to its partnerships with the White House and Federal agencies, FSIS has entered into a working relationship with the U.S. Public Health Service (PHS) and the Office of the Surgeon General. In April 2003, FSIS signed a Memorandum of Agreement with the Surgeon General and the PHS that allows expanded numbers of PHS Commissioned Corps Officers to be detailed to the agency. Not only will these officers help FSIS respond to foodborne disease outbreaks and assist in preventing foodborne illness, but they will assist in the agency's homeland security efforts as well. By working together, we will be able to better enhance public health.

Coordinated Research Efforts

Even within USDA, coordination and cooperation among agencies is vital. Because ensuring public health depends on sound scientific research, USDA's Agricultural Research Service (ARS) plays a critical role in assisting FSIS to achieve its public health and food safety goals. The research ARS conducts helps us to assess public health problems and to develop policies to reduce the risk of foodborne illness. For example, ARS' studies on the prevalence of *E. coli* O157:H7 were very helpful to us before we issued our *E. coli* O157:H7 policy initiatives last September. As another example, ARS' research studies are helping us to improve HACCP. By determining where contamination is likely to occur, we can then craft interventions that are effective in reducing contamination.

Northeast *Listeria* Outbreak

An example of the progress in coordinating efforts was an unprecedented investigation conducted with the CDC and State and local public health agencies on the Northeastern listeriosis outbreak that occurred in 2002. FSIS dispatched seven teams that also included State officials on September 25, 2002, to affected Northeastern States and used information provided by CDC to help target the collection of product samples. FSIS collected more than 400 samples of product and the environment for analysis in the course of the investigation. When it was first suspected that a turkey product caused the outbreak, FSIS took immediate, focused steps to identify plants that could potentially be the source of the contaminated product. Functioning as a true public health agency, FSIS spent an enormous amount of time and resources investigating this outbreak, including creating a team of more than 50 laboratory scientists, regional epidemiologists, Consumer Safety Officers, program investigators, compliance officers, field personnel, and headquarters management to work closely with CDC and State and local public health officials to locate the source. This investigation marked the first time that CDC staff participated as part of an FSIS food safety assessment team at an inspected establishment. CDC has publicly commended FSIS for its successful public health role in addressing this outbreak.

Training Partnerships

In 2001, USDA initiated a partnership with the Federal Law Enforcement Training Center (FLETC) in New Mexico to develop and provide training programs for FSIS employees. This training includes specialized safety courses specially designed for FSIS and an Instructor Verbal Judo Course designed to instruct them how to teach other employees how to better handle stressful situations they may encounter as part of their jobs. Most recently, an Assistant U.S.

Attorney and FLETC teamed up to provide training to 24 FSIS program investigators and managers on Federal judicial proceedings. The three-week course also included Leadership Training and Ethics for Law Enforcement Officers, sessions in Criminal and Civil Law and Advanced Investigative Methods and Techniques.

FSIS has also initiated a comprehensive two-year training and education effort designed to ensure that every FSIS employee fully understands their role in preventing or responding to an attack on the food supply. The Law Enforcement Academic Research Network (LEARN), which conducts the training, has stated that because it is being provided to such a broad base of our employees, this training effort is unparalleled in the Federal sector.

FSIS has a contract with Texas A&M University to train up to 150 Consumer Safety Officers. The four-week class covers scientific design of food safety systems, microbiology, utilizing scientific information, and report writing. The students receive three college credits from Texas A&M University.

USDA Partnerships

In addition to our partnerships with sister public-health agencies who have a stake in food safety and security, FSIS also works in coordination with other agencies within USDA. As a key component of the Department of Agriculture, the Food Safety mission area is able to ensure that food safety remains a priority during discussions of food nutrition, animal and plant health, marketing, research, and foreign trade programs under the purview of USDA.

Issues to Consider Before Altering the Current U.S. Food Safety System

In considering a single food safety agency, Congress must analyze the efficacy of the single food agency models in the countries that have adopted such paradigms, keeping in mind that the ultimate goal is to improve food safety and public health. We can re-configure the food safety system in an endless array of forms, but if food safety and public health is not improved, we have failed.

FSIS bases its policy decision on science, so the single food agency discussion boils down to one question: will there be a measurable benefit to public health? In other words, would such an effort save lives and reduce foodborne illness rates? As with any new food safety and security effort, we want to make sure that we maintain and continue improving on any progress that we have made to improve public health. We must make sure that any disruption to the current food safety system effectively improves food safety and public health. The data from countries that have consolidated their food safety agencies suggests that there is not a change in foodborne illness trends, and in some cases, the illness rates have increased, after the creation of a single food safety agency. As a scientist and a public health regulator, I strongly believe that our actions must have a positive impact on public health.

We must also consider the costs associated with any major overhaul to the U.S. food safety inspection system. As I am sure you are aware, consolidating multiple agencies is a monumental task, as can be seen in the examples of the recent creation of the Department of Homeland Security, as well as the creation of the Environmental Protection Agency in 1970. It is important to determine what the financial and human costs associated with a single U.S. food safety agency

would be, and to determine if this cost will best leverage funding for food safety. In addition, the effect such an effort may have on staffing numbers should also be considered.

Conclusion

We are proud of our accomplishments, particularly the declines in foodborne illnesses over the past few years, and must maintain and improve upon the progress that FSIS, FDA, and our food safety partners have made thus far. However, there is always more that can be done. As our food safety and security system continues to evolve, we must evolve with it. Our commitment to taking food safety and security to the next level is plain to see in the vision paper we released in 2003 titled *"Enhancing Public Health: Strategies for the Future."* This document is helping FSIS adapt to the changing needs of food safety and security and helping us ensure that our food safety and security system is capable of responding to and preventing foodborne illness and food hazards through the most effective means possible.

In conclusion, there are many outstanding questions to be addressed when considering fundamental changes (~~that may be needed~~) to the U.S. food safety system. FSIS is keenly aware of the sensitivity surrounding this issue, and particularly the viewpoint that the various agencies involved in food safety may cause confusion. We are also extremely concerned about not reversing the progress made in improving food safety and security thus far. FSIS is certainly investigating these issues and believes that before Congress decides to move further with any such initiative, these outstanding questions need to be seriously considered, researched, and answered.

Thank you for the opportunity to discuss our food safety and security program and our continued efforts in this area. We look forward to working with Congress to continue to keep the nation's food supply safe and secure and strengthen public health.