

FOOD SAFETY AND INSPECTION SERVICE

Submitted for the Record

**Statement of Dr. Merle Pierson, Acting Under Secretary for Food Safety
Before the Subcommittee on the Federal Workforce and Agency Organization**

Mr. Chairman 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, Acting Under Secretary for Food Safety at the U.S. Department of Agriculture (USDA). I am pleased to be here today with Dr. Robert Brackett, from the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA); Susan Hazen from the Environmental Protection Agency (EPA); and Richard V. Cano from the National Marine Fisheries Service (NMFS).

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. In USDA's view, the question of whether the various Federal agencies with food safety authorities are working together effectively to address food safety and security can be answered with a resounding, "Yes." The American food supply continues to be the safest in the world, and we are always striving to make it safer.

In my testimony, I will first address some of the issues raised in the March 2005 GAO report on overlap in the Federal food safety regulatory system and the concerns I have about that report. Then I will discuss FSIS' statutory authorities, the components of an effective food safety and

security system, the success of U.S. food safety and security efforts, and our cooperative efforts with our Federal, State and local partners.

The GAO Report

We appreciate the GAO's efforts in producing their March 2005 report on jurisdictional overlaps in the Federal food safety system. We all share a commitment to ensuring that the American food supply remains safe and secure.

FSIS would be concerned with any assessment that oversimplifies the food safety regulatory functions of FSIS and FDA, or is not clear on the inherent complexities and differences of our work. The breadth, complexity and size of the U.S. food production system lend itself to specialized government oversight. It is important to recognize that while FSIS and FDA inspection activities may seem similar, they are in reality vastly diverse due to differences in authorities and responsibilities.

While it is true that both FSIS and FDA have HACCP as a founding principle for food safety and public health, and it is also true that HACCP's general principles remain constant, food specific hazards differ greatly by product, thus necessitating differences in provisions and how the rules are applied. FSIS' HACCP regulations apply to meat and poultry products. FDA has two of its inspected commodities (seafood and juices) under mandatory HACCP. While there are commonalities in the FSIS and FDA rules, there remain significant differences between the two agencies' regulated industries under HACCP that dictate the necessity of distinctly different regulations.

Because the authorities and responsibilities at FDA and FSIS differ, the policies, procedures, and the training on inspection and enforcement strategies are also quite different. The products regulated by the two agencies are different, and many of the hazards and public health risks associated with those products are different. Additionally, there are significant differences in classification of the job series of individuals performing inspection duties. FSIS' inspection workforce includes technical as well as professional job series positions, while FDA positions are predominantly professional series. Moreover, the work environment of the two inspection workforces is different. As a result, the course content and educational strategies to train these two vastly different groups must by nature be significantly different.

There are two important points that we must keep in mind when considering jurisdictional overlap between FSIS and FDA, particularly with regard to dual jurisdiction establishments (DJE). First, the amount of food product, which falls within the overlap, is miniscule compared to the overall amount of product that the two agencies regulate independently. Correspondingly, the number of DJEs is also small, relative to the total number of establishments the agencies inspect. And second, any meat, poultry or egg product that falls within the jurisdictional overlap has already been inspected and passed by the USDA. Because of these key factors, the small amount of products in question pose a very low-risk to human health.

Finally, I am concerned that the Public Health Security and Bioterrorism Preparedness and Response Act (BT ACT) of 2002 is not completely understood. For example, meat, poultry and egg products that are within USDA's exclusive jurisdiction are not subject to the BT Act's

requirement that prior notice be given for imported food. In addition, while this Act gave FDA the authority to commission other Federal officials to inspect FDA-regulated foods, implementing an agreement between FSIS and FDA based on this Act would require a considerable amount of planning and work without any guarantee of improving public health. Since FSIS and FDA operate under different regulatory structures, roles and responsibilities would need to be carefully defined.

FSIS Statutory Authority

Since 1884, the regulatory structure of what is now the Food Safety and Inspection Service (FSIS) and its predecessor agencies has been designed to protect public health by preventing and containing any threats to the U.S. food supply. The Agency's 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. Under the authority of these Acts, FSIS provides continuous inspection of 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 jurisdiction over products that generate more than \$94 billion in farm cash receipts. This is an enormous responsibility and one the Agency takes very seriously.

Ensuring the safety of meat, poultry, and egg products requires a strong infrastructure. To accomplish this task, FSIS has a workforce of over 7,600 inspection and public health veterinary personnel stationed in approximately 6,000 federally inspected meat, poultry, and egg product

plants and import establishments every day. These public health inspection and veterinary personnel verify 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 comply with the Agency's statutory requirements. In addition, 4.2 billion pounds of imported meat, poultry, and processed egg products were presented for entry into the United States from 27 of 33 countries eligible to export to this nation in FY 2004. Overall, FSIS' responsibility covers a very large amount of product produced not only here in the United States, but throughout the world.

In addition to the inspection of products defined above, FSIS has many additional public health regulatory responsibilities. For example, the Agency sets policy requirements for meat and poultry label requirements and for slaughter and processing activities, such as plant sanitation and cooking of ready to eat products 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. FSIS also conducts Food Safety Education activities.

FSIS is also responsible for assuring that U.S. imported meat, poultry and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. While foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food hazards as is achieved domestically. To ensure the continued safety of imported products after initial equivalence is determined, FSIS

maintains a comprehensive system of import inspection and controls, which includes audits of a foreign country's inspection system and port-of-entry reinspection. At import establishments, 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 re-inspection 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 their inspection systems are equivalent to those of the United States.

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 and cold storage warehouses. 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, on average, suspends operations at more than 100 plants and refers approximately 30 cases for criminal prosecution to the Department of Justice annually.

FSIS' Role in the Food Safety and Security System

FSIS' Inspection System and Food Safety Successes

Our inspection system for meat and poultry is based on what we believe to be the most scientifically advanced process for food safety worldwide – the Pathogen Reduction/Hazard Analysis and Critical Control Points system (HACCP). HACCP is a preventive system that was implemented by the industry to put controls in place in their process in the most critical steps in their operation for purposes of food safety.

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 rooted in the premise that the most effective and efficient method of allocating resources is to base them on the assessment of greatest risks and hazards. The implementation of the Pathogen Reduction/HACCP regulations as well as a series of subsequent regulations and work force initiatives by FSIS have been both science and risk-based.

FSIS currently operates under a science-based system. Science allows for policy decisions to be continually updated based on technological advances and emerging threats. Science-based decision-making is objective and preventive in nature, and thus offers the best foundation for the

development of policies that will improve 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.

Our efforts are clearly on the right track, as evidenced by the decline in foodborne illness over the last seven years. This spring, the HHS' Centers for Disease Control and Prevention (CDC) reported continued reductions in foodborne illnesses from 1996 through 2004 stemming from *E. coli* O157, *Listeria monocytogenes*, *Campylobacter*, and *Yersinia*. Compared to the 1996-98 baseline illnesses caused by *E. coli* O157 decreased by 42%; *Listeria monocytogenes* dropped by 40%; *Campylobacter* fell 31%; and caused by *Yersinia* decreased by 45%. Overall, *Salmonella* illnesses have fallen by eight percent compared to the 1996-98 baseline.

The dramatic, multi-year reductions in illnesses from *E. coli* O157 mean the United States is now, in 2005, beating the Healthy People 2010 goal of one case per 100,000 persons, according to the CDC. This is six years early, and a remarkable national achievement. We are also very close to meeting the Healthy People 2010 goal set for illnesses from *Listeria monocytogenes* and *Campylobacter*.

This year's report indicates that reductions in foodborne illness reported in 2003 were not an isolated event and that sustained progress is being made toward reducing illness from very dangerous foodborne pathogens. The CDC attributes the changes in the incidence of these

infections in part to the control measures implemented by government and industry leaders, enhanced food-safety education efforts, and increased attention by consumer groups and the media.

Earlier this year, FSIS released data showing a 43.3% drop in the percentage of *E. coli* O157:H7 positive ground beef regulatory samples collected in 2004 compared with the previous year. Between 2000 and 2004, the percentage of positive *E. coli* O157:H7 samples in FSIS' regulatory sampling has declined by more than 80%. These reductions have been made possible in large part to FSIS' risk-and science-based approach to combat *E. coli* O157:H7 during the slaughter and processing stages.

Food Security

FSIS' century worth of experience has allowed the Agency to develop the expertise to protect the U.S. meat, poultry, and egg products supply wherever and whenever food security threats arise. However, FSIS does not carry out these efforts alone. FSIS works closely with the White House Homeland Security Council, the Department of Homeland Security (DHS), HHS-FDA, 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.

In addition, the President's Homeland Security Presidential Directive 9 has led to stronger working relationships among food regulatory agencies. This Directive, coordinated by DHS, 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.

To facilitate stronger interagency cooperation, information sharing is needed. This is why FSIS continues to build relationships with the intelligence and law enforcement communities, such as the Federal Bureau of Investigation, the Central Intelligence Agency and local law enforcement agencies. FSIS is providing information to these communities on food security concerns for intelligence collection and participating in information-sharing conferences sponsored by these agencies. Utilizing active intelligence will allow us to direct our financial, laboratory and human resources more efficiently, as well as inspection, in-distribution and outreach activities.

To further improve Federal and State government coordination to prevent and respond to any act of intentional contamination, FSIS entered into a cooperative agreement with HHS/FDA, DHS, and the National Association of State Departments of Agriculture to develop guidelines and procedures for State and local first responders and Federal food regulatory agencies. This interagency response plan will facilitate cooperation with State and local emergency efforts when responding to incidents involving the food supply. Following the development of these best practices, FSIS and its partners will test them through exercises and make improvements as necessary.

Another example of coordination with our partners is building a strong nationwide laboratory network that could quickly identify the presence, or absence of, a particular threat agent in a food commodity. To enhance this surveillance, FSIS has partnered with other food safety agencies

such as the FDA and its State counterparts to build an integrated laboratory system that would not only monitor the food supply and share data, but also assist in handling samples in the event of an emergency. This integrated system is known as the Food Emergency Response Network (FERN). The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that could be called upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the food supply. Such a system, in addition to providing an umbrella of protection for the food supply, would also help us identify and remove contaminated product from the marketplace quickly should an attack occur.

To further enhance food security, FSIS recently developed model food security plans as a valuable resource that can help plant operators identify preventive steps to minimize food security risks. FSIS strongly encourages all establishments to develop plans to fit their particular needs. The model plans are designed for meat and poultry slaughter facilities, meat and poultry processing plants, egg processing plants and import facilities. The materials are available on the FSIS web site (www.fsis.usda.gov) and are intended to be used with other FSIS food security resources, such as food security guidelines and food security checklists that were developed over the past three years. To assist the industry, especially small and very small establishments in developing food security plans, FSIS will conduct a series of training workshops throughout the nation in May, June and July 2005.

Recognizing employee training as another critical component of the government's food security efforts, FSIS is working with FDA, USDA's Food and Nutrition Service and Agricultural Marketing Service and related State and local regulatory personnel to provide joint training on

food security for field personnel from these agencies. This training is offered not only in 12 classroom sessions nationwide but also through CD-Rom and the Internet. It focuses on the vulnerabilities in the food supply and provides information on what government personnel should do in the event they identify an incident.

Coordination and Cooperation with Our Food Safety Partners

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.

We believe that cooperation, communication, and coordination are absolutely essential to ensure a safe and secure 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. I have already mentioned several situations in which FSIS partners with other Federal, State and local agencies to improve public health. I'll also discuss another example in which FSIS has partnered with another important public health agency to bolster our public health mission with the best available experts.

FSIS entered into a working relationship with the HHS U.S. Public Health Service (PHS) and the HHS Office of the Surgeon General. Two years ago, 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 do these officers help FSIS respond to foodborne disease outbreaks and assist in preventing foodborne illness, but they assist in the Agency's homeland security efforts as well.

The projects I have described above are highlights in the ongoing, sustained effort FSIS has undertaken to work in coordination with our food safety partners both here at home and around the world. We will continue to explore additional opportunities that will allow us to better protect the public health and better serve the American taxpayer.

Conclusion

FSIS is always willing to improve and change its systems to better meet a purpose and a goal. For example, FSIS has experienced considerable change over the past few years with the adoption of a HACCP based regulatory system and implementation of policies that have worked to provide a significant reduction in foodborne illness. It is essential that the agency's resources continue to be effectively directed towards those areas of greatest risk and not be diverted to efforts that have little potential for improving public health. Any such decisions must be based on science, and can be boiled down to one question: will there be a measurable benefit to public health? In other words, would any changes to the current food safety infrastructure save lives and reduce foodborne illness rates? Most importantly, we must ask ourselves is the public better served by FSIS, FDA and other agencies continuing to work closely together to better utilize resources and positively impact public health? Once again, our answer is a resounding, "yes".

We are proud of our accomplishments over the past few years and need to continue the progress that we and our partners here today – FDA, EPA, and NMFS – have made thus far. The strides made in protecting our food supply from intentional contamination, reduction in foodborne illnesses, as well as sustained reductions in the amount of pathogens on product samples collected and analyzed by FSIS, clearly indicate that our existing infrastructure and science-based policies are working and working well. We are committed to apply the best available science and management practices to continually seek to improve on our goal of protecting public health.

We appreciate the opportunity to discuss our food safety and security program and our continued efforts in this area. We are all here today because we want to protect public health by ensuring that the food on American tables is safe and secure. We look forward to working with Congress, GAO and our food safety partners to continue to keeping our nation's food supply the safest in the world.