UNITED STATES DEPARTMENT OF AGRICULTURE

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BEFORE THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

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Introduction

Mr. Chairman and Members of the Committee, I am pleased to have the opportunity to discuss the measures that the Department of Agriculture and the Food Safety and Inspection Service (FSIS), are taking to improve food safety, modernize our regulations, wisely utilize our resources, and maintain consumer confidence. Several years ago, we began a journey of change, modernization, and improvement regarding meat and poultry safety and inspection. While the journey continues, considerable progress has been made.

Under the leadership and commitment of President Clinton and Vice President Gore, this Administration has made great strides in improving food safety. In five and a half years, I have presided over many food safety accomplishments. First, when we reorganized the Department in 1994, we created a separate food safety mission area to ensure an arms-length regulatory system that is independent of our market promotion activities. As you know, since 1996, we have been in the process of replacing antiquated food safety regulations with the Pathogen Reduction and HACCP rule. This new science-based meat and poultry inspection system is the first modernization of the meat and poultry regulations since 1906 and it is helping to reduce outbreaks of foodborne illnesses. We have also overseen the creation of FORC-G and I am proud to serve as a Co-Chair on the President's Council on Food Safety, along with Health and Human Services Secretary Shalala and Neal Lane, Director of the White House Office of Science and Technology Policy. We have also played an important role in the formation and support of FoodNet and are key supporters of the Partnership for Food Safety Education.

Our food safety goal is to achieve the greatest possible reduction in the risk of foodborne illness associated with the consumption of meat, poultry, and egg products, consistent with available science and technology. Toward that end, we are applying resources in a prudent manner to make fundamental changes in industry responsibilities and FSIS inspection. We also want to build on our partnerships with other Federal agencies, the States, industry, consumer groups, academia, our employee organizations, and other interested segments of the public.

USDA Responsibilities

USDA's Food Safety and Inspection Service has a long, proud history of protecting the public health. Our mission is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and accurately labeled, as required by the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

FSIS provides inspection at approximately 6,000 plants that slaughter cattle, swine, sheep, goats, horses, chickens and turkeys, or that process a wide range of products including hams, sausage, stews, eggs and frozen dinners. In FY 1999, our domestic inspectors examined approximately 155 million carcasses in livestock slaughter plants, 8.4 billion carcasses in poultry slaughter plants, and 3.4 billion pounds of egg products for public consumption. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls. Annually, we review the equivalence of all foreign inspection systems in countries eligible to export meat and poultry to the U.S. Last year, during in-country reviews, we visited 265 foreign establishments and 33 foreign laboratories.

Reducing Threats to Public Health

Our food safety programs are designed to reduce all types of hazards in the food supply, whether they are chemical, physical, or microbiological. In recent years, we have emphasized the reduction of and control of pathogens that contribute to an estimated 76 million cases of foodborne illness reported by the Centers for Disease Control and Prevention. Pathogens cause foodborne illness and can have high fatality rates with illnesses such as listeriosis. This does not mean that we have ignored other hazards. FSIS continues to operate a strong residue control program to address chemical contamination, and continues to conduct inspection to remove diseased and unwholesome animals. These programs have been very successful and are recognized worldwide. And they need to continue, as scientists worldwide recognize that many of the newly emerging foodborne illnesses will be zoonotic – passed from one species to another – including from animals to humans. But experts agree that pathogens are the most serious threat to public health associated with food, and certainly with respect to meat and poultry products.

That is why, over the past six years, we have redesigned our food safety programs to target microbial pathogens. Organoleptic inspection – inspection by sight, touch or smell – is not sufficient in reducing these threats. Requiring plants to implement science-based preventive control systems targeted to meet performance standards set by FSIS, and conducting microbial testing to ensure those standards are met, has proven to be the best strategy. This approach, accompanied by a farm-to-table strategy that strives to reduce and control pathogens before animals reach FSIS-inspected establishments and after products leave the plant and enter consumer channels, has given us the best chance to reduce foodborne illness and strengthen consumer confidence.

We are not by any means ready to claim victory. The greatest possible reduction of microbiological contamination remains a challenging goal for a number of reasons. First, efforts to reduce microbial pathogens must constantly adapt to new technology, new research and emerging and evolving pathogens. In other words, addressing microbial pathogens is a continual, evolving process. Second, they can multiply or be introduced after a meat or poultry product leaves the federally inspected plant, particularly if a product is mishandled during transportation, storage, or in the home. That is why we are taking a farm-to-table approach.

Pathogen Reduction Strategy

Our pathogen reduction strategy is not a "one size fits all" strategy. We have developed different approaches based on a number of factors, including the individual pathogen and the risk it poses, the

type of the product relative to how much processing it has received and what degree of additional preparation it will receive that will affect pathogen loads. Our strategy is also highly dependent on the degree of technological development that exists relative to pathogen reduction. As research provides better and faster testing methodologies and effective risk assessment and risk management strategies, we can adjust our pathogen reduction strategies accordingly. With additional research and testing, for example, much more may be possible on the farm or ranch, earlier in the farm-to-table continuum.

Raw Products

For raw products, our goal has been to reduce levels of contamination of key pathogens to the greatest extent possible. Thus far, we have chosen to establish pathogen reduction performance standards for *Salmonella* because it is a major pathogen of concern, is present on virtually all classes of raw meat and poultry products in numbers large enough to detect, and effective methods are available to test for the pathogen. Studies show that technologies that reduce the prevalence of *Salmonella* on carcasses would lead to a reduction in other pathogens as well. Repetitive failures to meet the performance standard is an indicator that the plant's HACCP plan is not adequate.

The *Salmonella* performance standards provides an incentive for producers of raw meat and poultry products to establish and maintain HACCP plans that reduce and control the prevalence of *Salmonella* on their products. The pathogen reduction performance standards are based on FSIS baseline surveys on the prevalence of *Salmonella* in raw products. FSIS conducted a number of baseline surveys in order to determine the prevalence of various pathogens in various products. In addition, over time, baseline profiles for meat and poultry provide a basis for measuring the effectiveness of changes in slaughtering and processing procedures on microbial contamination of raw products. Establishments must achieve the applicable performance standard consistently through appropriate and well-executed controls. The *Salmonella* pathogen reduction performance standards in the HACCP regulation apply a uniform policy principle: all slaughter and ground product plants must achieve at least the industry baseline level of performance with respect to *Salmonella* for the product classes they produce. This approach encourages progress on pathogen reduction across all species.

The data we have collected since HACCP implementation has proven our strategy effective and fair. It is significant that if we were setting the performance standards today, they would be substantially lower than those originally established. Plants have made significant progress in reducing the prevalence of *Salmonella* in raw products. I want to commend the industry for its efforts. I will discuss our data in greater detail shortly to show our pathogen reduction efforts are working.

We intend to reassess whether these standards should be tightened, and whether there are additional pathogens for which pathogen reduction performance standards should be set. In fact, in October, we will complete a baseline survey on *Campylobacter* in poultry, and will begin the process of deciding whether to develop performance standards for that pathogen.

Ready-to-Eat Products

Our strategy for ready-to-eat products differs considerably from our strategy for raw products, because consumers may not apply additional cooking steps to kill pathogens. The performance standards we have established for ready-to-eat products are not pathogen reduction performance standards, but are designed to remove unsafe, adulterated products from the marketplace. In this case, the presence of a pathogen means the process to render the product ready-to-eat has failed or the product has been recontaminated.

FSIS began testing ready-to-eat products for *Salmonella* in 1983 and *Listeria monocytogenes* in 1987. The following product categories are included in the *Listeria monocytogenes* and *Salmonella* monitoring programs: (1) sliced ham and luncheon meat, (2) roast beef, cooked beef, and cooked corned beef, (3) small-diameter cooked sausage, (4) large-diameter cooked sausage, (5) cooked, uncured poultry, (6) salads and spreads, (7) dry and semi-dry fermented sausage, and (8) beef jerky.

Plants are encouraged to hold products targeted for *L. monocytogenes* and *Salmonella* testing by FSIS until results are available so that potentially contaminated products do not reach consumers. However, in the event that FSIS discovers a positive sample and the product was not held by the plant, FSIS requests that the plant voluntarily initiates a product recall. In addition, when a positive sample is found, FSIS conducts follow-up testing of products produced by the plant. Monitoring samples is one method FSIS uses to verify compliance with our regulations.

Special Requirements for *E. coli* O157:H7

There are exceptions to our basic strategy to address pathogens in raw and ready-to-eat products. *E. coli* O157:H7 in ground beef and other non-intact beef products are examples. This pathogen presents unique public health concerns with the consumption of certain beef products. Thus, FSIS declared it an adulterant in raw ground beef in 1994. FSIS expanded this designation to other non-intact beef products in January of 1999 based upon new scientific data. This is the first and only time that a pathogen has been declared an adulterant in raw meat and poultry products. This action was taken because of the nature of the pathogen and the manner in which the product is prepared by consumers. Studies by the Agricultural Research Service and industry demonstrate that the organism is far more prevalent than previously understood and HACCP-based processing technologies can significantly reduce contamination. To further prevent *E. coli* O157:H7 related illnesses, we advise consumers to use a thermometer and cook ground beef to an internal temperature of 160 degrees F, consistent with our farm-to-table strategy.

Our experience with *E. coli* O157:H7 is a good example of why a "one size fits all" policy does not work for pathogen reduction.

Role of HACCP

HACCP is the centerpiece of our pathogen reduction strategy because it provides a framework in which industry can develop and implement controls to eliminate or reduce and control hazards. Under this system, each meat and poultry plant is responsible to identify all food safety hazards reasonably likely to occur in its operation, taking into account all hazards—microbiological, chemical, and physical. The plants then establish critical control points, at which steps are taken to

prevent, reduce or control hazards. HACCP and performance standards go hand-in-hand—HACCP provides a system for preventing and controlling foodborne hazards, and the performance standards provide a benchmark that the HACCP system must achieve.

Industry began HACCP implementation in 1998 based on plant size. The completion of very small plant implementation in January 2000 brought 100 percent of U.S.-inspected meat and poultry products under the HACCP system. We are seeing significant reductions in *Salmonella* prevalence for large and small plants. We expect to see similar results from HACCP at the very small plants. HACCP is clearly working to achieve our food safety goals.

***Salmonella* Data**

With the PR and HACCP rule, the prevalence of *Salmonella* on raw products has been substantially reduced. All categories tested showed a marked decrease. For example, *Salmonella* has been reduced on chicken carcasses by more than 50 percent and by one-third on ground beef. The prevalence on ground turkey is also very impressive – a nearly 40 percent reduction. These products account for the majority of domestic production. Industry has clearly risen to meet the challenge, with the result being safer food for Americans. One of the strongest aspects of HACCP is that it provides for constant improvement. As hazards change and new hazards become known, plants must adjust their plans accordingly.

Prevalence of *Salmonella* in meat and poultry products: Post-HACCP implementation results from large and small plants from July 1, 1999, through June 30, 2000

Class of Product	Pre-HACCP Baseline Studies	Post-HACCP implementation *Salmonella* Prevalence (%) n=number of samples
Broilers	20%	9.9% (n=9,231)
Hogs	8.7%	7.7% (n=3,685)
Cows and Bulls	2.7%	1.6% (n=1,450)
Steers and Heifers	1.0%	0.2% (n=902)
Ground Beef	7.5%	5.0% (n=9,010)
Ground Turkey	49.9%	30% (n=901)

HACCP – The Next Steps

Now that initial HACCP implementation is complete, FSIS is developing a strategy to improve the quality and effectiveness of HACCP. We are exploring ways to improve the quality of industry's HACCP programs. In addition, we must improve the effectiveness of FSIS under HACCP.

For example, we are seeing a large range in the quality of HACCP plans, ranging from excellent to poor. We are exploring options to address this problem and have asked industry organizations for

assistance. Another problem we are seeing involves our own inspection force. Some of our inspectors need more training to better understand and evaluate the hazard analysis process, for example. Also, we must address how inspectors evaluate the various data generated through HACCP and how FSIS uses the data to determine whether a plant's systems are working as intended.

We also must refine what is addressed under HACCP versus other plant process control and quality assurance systems. As I mentioned, HACCP can be adapted to new food safety concerns. As part of these next steps, we are exploring how plants can best prevent *Listeria monocytogenes* in ready-to-eat products. FSIS is also looking at the broad subject of residue monitoring and control by slaughter plants in a HACCP environment. A public process will be used to explore and develop our strategy.

We are developing a HACCP-based Inspection Models Project (HIMP), that tests whether alternative models of inspection can do a better job than our traditional inspection system. The results to date are encouraging and show that we can develop a model of inspection that will significantly improve public health and other consumer protections. I want to emphasize that the models project will only proceed if there continues to be objective data that shows it works at least as effectively than the traditional inspection system. HIMP is not about lowering standards or cutting back on inspectors. It's about finding better ways to protect the public, and having the data to ensure continued consumer confidence.

Risk Assessments

In addition to improving the effectiveness of HACCP, another way we are improving our ability to address pathogens is by relying more heavily on microbial risk assessments. Regulatory agencies seldom have all the information needed to make policy decisions and often are forced to make decisions based on the best scientific information available at the time. Risk assessment helps to organize scientific information in order to characterize the nature and likelihood of harm to the public. Such assessments also are tools to help target risk management strategies.

Over the past several years, Federal agencies have made great strides in the science of microbial risk assessment. It has taken some time because there are many challenges in applying risk assessment methods to microbial pathogens. One challenge relates to the fact that unlike chemical contaminants, bacteria can multiply and produce toxins as conditions change. In addition, we have many data gaps currently that limit the precision we can achieve through risk assessments.

Despite these challenges, we are making good progress. In 1998, we completed a risk assessment on *Salmonella Enteritidis* in eggs and egg products. We are close to completing a risk assessment for *E. coli* O157:H7 in ground beef, and FDA has taken the lead on a joint agency risk ranking of *Listeria monocytogenes* in ready-to-eat products.

With the information contained in these risk assessments, Federal agencies that set food safety policy can establish better performance standards and better determine where to apply their resources to get the best return in terms of public health improvement.

Farm-to-Table Strategy

I would like to turn from in-plant improvements to what we are doing farm-to-table. Food safety experts, including the National Academy of Sciences and the National Advisory Committee on Microbiological Criteria for Foods, agree that pathogen reduction requires a farm-to-table approach. While HACCP is designed to address and achieve improvements at the plant level, additional initiatives at other points in the food production chain are also needed. FSIS has already begun a number of projects to address these other points, including encouraging industry to develop on-farm pathogen prevention models, working with the Food and Drug Administration (FDA) on the retail Food Code, which is a model code for all retail and food service operators, and requiring safe handling instructions on products for consumers. Now that initial HACCP implementation has been completed in U.S. slaughter and processing facilities, FSIS has the opportunity to make further progress in implementing other aspects of its farm-to-table strategy.

USDA supports research and educational activities that promote the adoption of voluntary, industry-implemented food safety and quality assurance programs that improve food safety at the farm, and we recently co-sponsored a very successful conference in St. Louis, Missouri, on animal production food safety.

With HACCP clarifying industry responsibilities for food safety, slaughter plants are focusing more on the potential hazards in incoming animals while developing and executing their HACCP plans. This is already affecting the relationships between producers and their customers, the packers, by providing producers with an incentive to address food safety.

Our intent at FSIS has been to provide information to all producers about HACCP and how its implementation might affect their ability to market their animals for slaughter. For example, we have provided information on residue avoidance through adoption of quality assurance practices and programs. As small producers have fewer resources, FSIS is providing more attention to assisting them with applying HACCP concepts to their operations, as well as working closely with State agencies and local extension offices.

We have a steep learning curve when it comes to finding ways to reduce pathogens. We recognize that reducing pathogens in animals is a significant challenge. Scientific information is lacking to demonstrate what is routinely effective and economically feasible at the production stages to reliably eliminate or at least substantially reduce pathogens on carcasses. We must develop plans based on the best information we have today and update them as new scientific information becomes available.

New Technology

FSIS encourages research that will lead to new technologies to better enable plants to meet FSIS-established performance standards, as well as to help both industry and government to rapidly, accurately, and inexpensively detect pathogens. Examples of technologies that help to reduce or eliminate pathogens are steam vacuuming, steam pasteurization, and TSP washes. Aseptic packing systems are another example of technologies that help prevent the introduction of pathogens.

The Agency recognizes that in order to foster innovation, it cannot be an obstacle, so FSIS reviewed its policies and procedures governing new equipment and in-plant technologies and eliminated many burdensome requirements. As a result, we approved many new technologies this year. For instance, FSIS approved the use of irradiation for meat products and also provided for the use of certain food additives (Sodium Acetate, Sodium Lactate, and Potassium Lactate) to inhibit the growth of pathogens, like *Listeria monocytogenes*. Neither food additives nor irradiation alone are the answer – no one tool or technology is – but, used properly, they provide additional opportunities for an increasingly safe food supply.

FSIS also recognizes that for technology to be most beneficial, it must be accessible to all. Although new technology is almost always designed for large plants, FSIS is placing special emphasis on seeing new technologies adapted so they can be used economically in small and very small plants.

Future Technology Needs for FSIS

FSIS has held three scientific and technical conferences and one public meeting to discuss the need for new technology that can assist the Agency meet its goal for reducing foodborne illness and protecting the public health.

Because microbial performance standards are taking on heightened importance, the Agency and industry need new microbial detection technology for use in our laboratories. Quantitative detection methods are needed that are practical, inexpensive, sensitive, and that provide rapid results, as are methods that can detect more than one pathogen. In addition, the potential for on-line detection in slaughter and process plants needs to be developed. Similar new technologies are needed for chemical residues.

Partnerships for Increased Food Safety

In striving for a seamless farm-to-table food safety system, we are forging ties between animal producers and slaughterhouses and are looking more closely at our role once product leaves federally inspected establishments. Hand-in-hand with this, we are strengthening ties with our state and local counterparts. USDA also is interested in ensuring that its policies and procedures are as consistent as possible with the other Federal bodies regulating food safety.

We are working closely with FDA on a number of issues including streamlining the approval process for food ingredients, such as food and color additives, and sources of radiation, by ending the requirement that they be approved separately by both the FDA and FSIS. Previously, once FDA approved a food ingredient, FSIS had to conduct separate rulemaking in order for it to be approved for use in meat or poultry. This is the latest in a series of regulatory reform initiatives published by the Agency to: (1) improve food safety, (2) make regulations less burdensome and easier to use, (3) make regulations more consistent with Hazard Analysis and Critical Control Point (HACCP) Systems, and (4) eliminate outdated regulations.

Another joint effort with FDA was last year's Memorandum of Understanding to facilitate the exchange of information at the field level about food establishments and operations that are subject to the jurisdiction of both agencies. District offices of each Agency will notify their counterparts of food safety recalls, instances of product contamination and mislabeling, and conditions at facilities that could result in unsafe or unwholesome food.

In an effort to facilitate information exchanges with the Centers for Disease Control (CDC), we placed an FSIS employee in CDC's Atlanta office. In return, CDC placed one of its employees at FSIS' headquarters.

To educate consumers about cooking foods to the correct temperature and promote the use of food thermometers in the home, I announced the kick-off of the ongoing "Thermy" national campaign in May. The campaign features a cartoon thermometer called "Thermy" that proclaims, "It's Safe to Bite When the Temperature is Right."

Conclusion

Though we have made tremendous gains over the last several years, we are not content to sit back and congratulate ourselves. As long as anyone is getting sick from the products we regulate, there is room for improvement. We will continue to take whatever steps are necessary to improve the safety of meat, poultry, and egg products and look forward to working with Congress, other government agencies at the Federal, State and local levels, industry, and consumers, to do so.