

FOOD SAFETY AND INSPECTION SERVICE

Statement of
Dr. Elisabeth Hagen, Under Secretary for Food Safety
Before the
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Introduction

Mr. Chairman, Ranking Member Farr, and Members of the Subcommittee, I am Dr. Elisabeth Hagen, Under Secretary for Food Safety.

I am pleased to appear before you today and appreciate the opportunity to discuss the status of the Food Safety and Inspection Service's (FSIS) programs and the fiscal year (FY) 2012 budget request for food safety within the U.S. Department of Agriculture (USDA).

Who We Are

As the public health regulatory agency of the USDA, FSIS is responsible for ensuring that our Nation's domestic and imported commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome, and accurately labeled and packaged. The work that we do affects every American who puts meat or poultry on the dinner table.

FSIS inspection program personnel form the backbone of FSIS' public health infrastructure in domestic processing and slaughter establishments, laboratories, and import houses throughout

the country. In FY 2010, the agency employed more than 9,800 personnel, including more than 8,000 in-plant and other front-line personnel protecting public health in approximately 6,200 Federally inspected establishments nationwide.

Our employees are our greatest asset and strength. We are only as effective as our dedicated workforce. Just as they are committed to keeping America's food supply safe, we are committed to them. FSIS has effectively filled mission-critical positions at the agency, such as public health veterinarian (PHV) positions. Between December 2009 and December 2010, the vacancy rate for PHVs (even without applying other-than-permanent coverage) declined by almost four percent, from 11.5 to 7.7 percent. And over the last two years, since December 2008, the PHV vacancy rate has decreased by almost eight percent, from 15.6 to 7.7 percent.

Our Statutory Authorities

FSIS is charged with enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act (EPIA), and the regulations promulgated under these laws. These laws lay out which specific meat products that the agency is charged with inspecting by naming those species that are deemed "amenable", how we regulate the labeling of meat and poultry products, and how we ensure the safety of the products under our authority.

We share authority under the EPIA with the Food and Drug Administration (FDA), which regulates eggs in their shells, or shell eggs. FSIS, on the other hand, regulates processed eggs and egg products. Shell eggs that are broken at an official FSIS-regulated egg products plant are

pasteurized and tested for *Salmonella*. FSIS also enforces the Humane Methods of Slaughter Act (HMSA), which requires that all livestock be handled and slaughtered in a humane manner.

Authorized by portions of the Agricultural Marketing Act, FSIS also provides voluntary fee-for-service inspection of certain products. For example, we provide voluntary inspection and certification for wholesomeness relating to the slaughter and processing of exotic animals. We also provide voluntary inspection and certification of food products for dogs, cats, and other carnivorous animals.

FSIS Presence in the Field

The high volume and the nature of the products that FSIS inspects demand an in-plant inspection presence. Therefore, FSIS inspection program personnel are present for all domestic slaughter operations, inspecting each and every livestock and poultry carcass and each meat, poultry, and egg processing establishment at least once per shift.

During FY 2010, FSIS inspection program personnel ensured public health requirements were met in establishments that slaughter and/or process 147 million head of livestock and nine billion poultry carcasses. Inspection program personnel also conducted eight million food safety and food defense procedures to verify that the systems at all Federal establishments met food safety and wholesomeness requirements. During FY 2010, inspection program personnel condemned more than 451 million pounds of poultry and more than 493,000 head of livestock during ante-mortem (before slaughter) and post-mortem (after slaughter) inspection.

In support of in-plant personnel in 6,200 Federally inspected establishments, FSIS employs a number of other field personnel, such as laboratory technicians and investigators. Program investigators conduct surveillance, investigations, and other oversight activities at food warehouses, distribution centers, retail stores, and other businesses that store, handle, distribute, transport, and sell meat, poultry, and egg products to the consuming public. These in-commerce businesses do not operate under grants of inspection and are not inspected on a daily basis by FSIS. However, the agency's oversight of FSIS-regulated products moving in consumer distribution channels is a vital part of our mission to protect public health.

The agency ensures the safety of imported products through a three-part equivalence process that includes 1) analysis of an applicant country's legal and regulatory structure, 2) on-site equivalence audits of the country's food regulatory systems, and 3) continual point-of-entry re-inspection of products received from the exporting country. In FY 2010, FSIS personnel at the U.S. border were presented with approximately 3.2 billion pounds of meat and poultry products from 29 eligible countries and approximately 22.4 million pounds of egg products from Canada for re-inspection.

FSIS also regulates intrastate commerce through cooperative agreements with the 27 States that operate meat and poultry inspection programs, conducting reviews of these programs to ensure that they are "at least equal to" the Federal program. FSIS recently released the results of its annual review of State program self-assessments, and its triennial on-site review of each State program (nine programs annually), and determined that all of these States met the "at least equal to" standard.

FY 2012 Budget Request for Foodborne Illness Prevention

There is no more fundamental function of government than keeping its people safe from harm, and as I have outlined, FSIS personnel ensure the safety, security, and wholesomeness of meat, poultry, and processed egg products in intrastate and interstate commerce, and at ports of entry.

I'd like to continue my testimony today by discussing my most important commitment to Congress, consumers, and industry alike: preventing foodborne illness.

Prevention is the guiding principle of USDA's Office of Food Safety and the Food Safety Inspection Service. And to prevent consumers from falling victim to foodborne illness requires taking a proactive approach to food safety. And that is precisely what FSIS strives to do every day; protect American families from foodborne hazards that can find their way into FSIS-regulated products – pathogens like *E. coli* O157:H7, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes* – through a systematic and coordinated strategy that includes rigorous inspection, product testing, risk analysis, vulnerability assessments, and enforcement.

There are still far too many people getting sick and dying from the food they eat, and for that reason we must continue to strengthen our prevention methods. The Centers for Disease Control and Prevention (CDC) estimates that 48 million people get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases.

The latest foodborne illness statistics show that we are doing better and better. According to the most recent (2009) data from the CDC Foodborne Diseases Active Surveillance Network, or FoodNet – which collects data from 10 State health departments, FSIS, and the FDA – the incidence of human illnesses from pathogens transmitted commonly through all food has declined compared with the baseline established between 1996 and 1998. This data indicates that the incidence of illnesses from *E. coli* O157:H7 decreased by 41 percent, *Campylobacter* decreased by 30 percent, *Listeria* decreased by 26 percent, and *Salmonella* decreased by 10 percent. However, any number of illnesses is unacceptable, and there is much more that we can do to prevent the spread of foodborne pathogens.

Investing in food safety can save money as well as lives. Estimates of the costs of foodborne illness vary widely, but it is clear that they are substantial and amount to billions of dollars annually. Foodborne illnesses can also result in loss of confidence by domestic and foreign consumers in the U.S. food supply, an indeterminate cost that cannot be understated. As Benjamin Franklin once said, “An ounce of prevention is worth a pound of cure,” and this applies to the health of our nation, as well as the health of our economy. As a health care professional, I understand that the monetary cost of medical care for individuals with foodborne illness can also be a great burden. But the emotional cost can be even greater, sometimes resulting in death. So while foodborne illness costs society billions, it’s hard to put a price on losing a child or a family member.

That is why the FY 2012 budget proposes a \$5.5 million increase to expand Hazard Analysis and Critical Control Point (HACCP) regulatory sampling for key pathogens and conduct an

additional traditional baseline study. This increase will allow FSIS to improve surveillance of foodborne pathogens of human-health concern in FSIS-regulated products, develop more timely estimates of pathogen prevalence, and ultimately focus resources more efficiently and effectively.

The budget also includes an increase of \$700,000 to support testing for non-O157 Shiga-toxin producing *E. coli* (STEC). Thanks to new estimates by the CDC, we now know that strains of STEC other than O157 are causing approximately 112,752 human illnesses and 271 hospitalizations. Like illnesses caused by O157, other strains of STEC can cause Hemolytic Uremic Syndrome, which can cause kidney failure. And like O157, these strains are highly pathogenic: a low infectious dose of STEC – just a few cells – can lead to disease. FSIS had first-hand experience with non-O157 STEC when on August 28, 2010; Cargill Meat Solutions Corp. in Pennsylvania recalled approximately 8,500 pounds of ground beef products that may have been contaminated with *E. coli* O26 after FSIS linked these ground beef products with three illnesses, including two in Maine and one in New York. This was the first definitive outbreak and recall associated with non-O157-contaminated beef in the United States. We cannot wait for another public health emergency to address the range of *E. coli* threats in ground beef that currently exist, and therefore, the budget includes an increase of \$700,000 to address these pathogens of public health concern.

The FY 2012 budget also includes an increase of \$4.3 million to strengthen the Public Health Epidemiology Program. This will help the agency respond more quickly to current public health needs, including the rising frequency of multi-jurisdictional foodborne illness investigations.

Budget Reductions and Savings

In the current economic climate, FSIS is doing its part to do more with less, and is working to achieve savings by streamlining operations and making other efficiencies.

As Secretary Vilsack stated in his testimony before this Subcommittee, we are proposing a budget for FY 2012 which reflects the difficult choices we need to make to reduce the deficit while supporting targeted investments that are critical to long-term economic growth and job creation. It looks to properly manage deficit reduction while preserving the values that matter to Americans. Thus, the requested budget for FSIS is \$1 billion, a reduction of about \$7 million below 2011. The requested level is adequate to fully fund inspection activities and includes an increase of \$27 million to improve our capability of indentifying and addressing food safety hazards and preventing foodborne illness.

In FY 2009 and 2010, FSIS worked with outside experts on an organizational assessment of non-frontline positions. An analysis of the findings has identified 37 full-time equivalent positions that can be eliminated to improve supervisory span of control, manage reduced workloads and/or eliminate senior-level analyst positions that are no longer required as the agency's programs evolve. FSIS expects to save \$4.5 million by 1) refraining from backfilling open positions resulting from attrition, 2) restructuring functional areas to streamline operations, and 3) consolidating staff and resources to eliminate redundant positions.

FSIS is implementing a comprehensive plan to realign and make our sampling programs more efficient, building on the implementation of the Public Health Information System (PHIS). PHIS will contain several components that will serve as the foundation for the implementation of a Laboratory Information Management System and allow for the achievement of cost efficiencies with sampling programs and laboratory testing. FSIS expects to save \$1 million through this effort.

FSIS currently collects and analyzes approximately 125,000 samples per year. As time is a critical element in the analysis process, laboratory sample packages are sent overnight from the inspection facility to one of three agency field labs. Like the sample packages sent to the labs, currently the empty lab containers are sent back using express mail. Prompted by a SAVE Award proposal submitted by an FSIS food inspector, the agency will start returning laboratory sample containers using ground transportation instead of express mail, saving approximately \$350,000 each year.

FSIS maintains more than 4,000 broadband connections (end-points) nationwide, and in U.S. Territories. The agency diligently works to provide the most cost-effective service for its nearly 10,000 fixed-site and mobile Federal and State users, including more than 8,000 inspection program personnel. As new broadband services become available, FSIS will continue to examine lower cost options that provide the same or better service, as well as opportunities to consolidate. FSIS anticipates saving \$3.5 million through this effort.

Since FY 2002, FSIS has worked to improve the overall security and capacity of its three regulatory sampling laboratories. This expansion effort has enabled FSIS to build an infrastructure that could respond to potential security threats targeting the public food supply for FSIS regulated products. In addition, since FY 2008, the agency has dedicated resources to purchase equipment that provides FSIS labs with the capability and capacity to perform the toxin and chemical testing standardized by the Food Emergency Response Network, or FERN. FERN is a Federal, State, and local partnership that provides ongoing surveillance and monitoring of food, and is capable of conducting the extensive sampling that is necessary in the event of a terrorist attack, act of nature, or hoax that affects the food supply. The capacity-building phase of these efforts has been completed and the maintenance and operational phases, which require considerably fewer resources, have begun, thereby saving \$5.6 million. In addition, we expect \$4.1 million in savings from a redirection of funding for FERN cooperative agreements.

Tools

FSIS cannot carry out its public health mission without the proper tools. One of the agency's most powerful tools is data: the ability to collect, consolidate, and analyze data is crucial to protecting public health. For this reason, FSIS has developed and is launching a dynamic web-based data analytics system called PHIS. PHIS will integrate and automate our paper-based business processes and significantly improve the way FSIS detects and responds to foodborne hazards by enabling FSIS field personnel to input inspection findings and sampling data directly into the system on a near real-time basis. The budget request includes \$3.6 million for PHIS staffing costs; and \$13 million for the Public Health Data Communications Infrastructure System, which provides the day-to-day functionality to PHIS and other FSIS applications.

We also enhance food safety through updated policies. For example, we are exploring how best to address non-O157 Shiga toxin-producing *E. coli* (STEC) in raw non-intact beef products. In addition, FSIS is working on the implementation of revised *Salmonella* and new *Campylobacter* performance standards for turkeys and broilers, or young chickens. With these performance standards, FSIS is encouraging establishments to make continued improvement in the occurrence and level of these pathogens in their products. These standards, once fully implemented, are expected to prevent as many as 25,000 illnesses each year.

Moreover, FSIS is working on a new policy to ensure that meat and poultry products that test positive for dangerous pathogens no longer reach store shelves or consumers' tables. FSIS is drafting a notice requiring that product being tested for dangerous pathogens is held at FSIS-regulated slaughter or processing facilities until the test results are confirmed negative. This policy could have prevented 22 recalls during FY 2009 and FY 2010, so we can expect fewer recalls by industry and increased consumer confidence in the safety of the food supply.

Finally, FSIS is deeply committed to ensuring the humane treatment of all animals that are presented for slaughter, and therefore continually updates its HMSA enforcement protocols. FSIS inspection program personnel are trained to identify problems and are obligated to take immediate enforcement action when a humane handling violation is observed. They also understand that if an animal becomes non-ambulatory disabled at any time prior to slaughter, it must be condemned and promptly euthanized. In December 2010, FSIS announced the following new measures related to humane handling: enhanced humane handling training for

inspection program personnel; a notice to inspection program personnel clarifying existing rules related to non-ambulatory cattle; a commitment to respond to and solicit comments on two humane handling related petitions; a request that USDA's Office of Inspector General audit industry appeals of noncompliance records and other humane handling enforcement actions by FSIS; and the future appointment of an Ombudsman in the Office of Food Safety specifically for humane handling issues.

People: Consumer Outreach

Our goal is to make the policy changes and scientific breakthroughs necessary to yield a safe food system, but consumer education and outreach is a key to our preventive strategy.

Consumers will always be FSIS's primary focus. Protecting consumers—U.S. and international—from foodborne illness drives our every move. The agency resolves to ensure that every activity it conducts has a direct impact on public health.

Prevention is our primary focus, as I have said; but until these primary preventive measures work 100 percent of the time – until they're 100 percent effective – it's also our responsibility to give consumers the information that they need to keep themselves and their families safe from foodborne illnesses. Thus, our preventive methods include outreach to at-risk and underserved consumers and communication with our stakeholders via messaging tools such as recall and news releases, public health alerts, podcasts, newsletters, public meetings, printed brochures, and public service announcements.

FSIS is partnering with the Ad Council to produce a multi-media, national public service advertising campaign to raise awareness of the dangers of foodborne illnesses and to effect change in food handling behaviors at home. We are building this campaign with representatives of other Federal agencies, academia, and consumers and industry who are members of the expert panel convened by the Ad Council. The campaign will be unveiled this summer.

We will also conduct consumer focus group studies to measure consumer understanding of labeling and other public health messaging and develop new outreach and education strategies based on the results.

The Office of Food Safety and FSIS have increased outreach to clinicians, public health professionals and consumers on actions to reduce the risk of foodborne illness. In my role as Under Secretary and as a medical doctor, I am keenly aware that clinicians and public health professionals are uniquely positioned to have a positive impact on foodborne illness prevention. I have therefore already reached out to the medical and public health community in order to build bridges, and will continue to do so in the future.

Collaboration with Food Safety Partners

The final measure of FSIS' success is the reduction of illnesses caused by meat and poultry products. Pathogen reduction is central to reducing illnesses and measuring the prevalence of pathogens is an important way for FSIS to measure progress towards its ultimate objective, reducing foodborne illness.

FSIS is working with FDA, the CDC, and the National Center for Health Statistics to develop Healthy People 2020 goals and timelines for a variety of foodborne pathogens, including *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Campylobacter*, as well as emerging pathogens of public health concern.

Our State and local public health and regulatory partners are with us on the front lines in our battle to keep food safe. FSIS conducts foodborne illness investigations in response to situations in which an FSIS-regulated product may be associated with human illness. One of the ways we become aware of a possible link between an FSIS-regulated product and human illnesses is through notification by local, State, territorial and international public health officials. If public health officials identify a possible association between human illness and an FSIS-regulated product through surveillance, they typically contact FSIS to request assistance with the investigation. But we work with our partners daily to protect public health. Our epidemiologists are stationed throughout the country and we have personnel assigned on a full-time basis at CDC in Atlanta. By digging our well before we are thirsty, building relationships before a crisis, we are better prepared to respond to illness outbreaks. FSIS inspection program personnel and investigators also work in coordination with local, State and territorial health or agriculture department personnel during domestic traceback investigations. According to the Association of Food and Drug Officials' 2009 State Food Safety Resource Survey, state and local regulatory agencies performed nearly 5 million inspections, 400,000 samples, and 56,000 investigations in a single year – leading to more than 1,200 recalls in the interest of public health. This effort by State and local agencies is vital to the success of FSIS foodborne illness and traceback investigations.

While we work daily with our food safety partners in the field, we are also working at a policy level on the Food Safety Working Group, an effort initiated by the President to better coordinate and improve our food safety laws. This Working Group has been a vehicle to discuss and develop cross-cutting government-wide issues focusing our food safety system on the prevention of foodborne illness.

Small and Very Small Plant Outreach

FSIS conducts outreach efforts and issues guidance aimed at helping small and very small slaughter and processing plants to comply with FSIS regulations. Establishments with 500 or fewer employees represent more than 90 percent of the FSIS-regulated establishments and we have taken a multi-pronged approach in order to ensure that they have the information they need to be successful.

In FY 2010, FSIS launched its Small Plant Help Desk, which responded to 2,277 inquiries during the fiscal year. The agency also distributed 24,000 copies of its proposed HACCP validation guidance and the FSIS General Food Defense Plan. FSIS published a monthly edition of the, “Small Plant News,” including a variety of topics targeted to meet the needs of small and very small plants operators, such as the importance of holding products while test results are being confirmed, how to develop food defense plans, and how to validate HACCP plans. FSIS developed 12 new podcasts on food safety issues for small and very small operators, and conducted exhibits at 23 industry events to share outreach materials with small and very small

operators. Through these efforts, we reached approximately 55,225 industry operators in FY 2010.

Since my confirmation as Under Secretary for Food Safety, I have visited numerous FSIS-regulated establishments in rural areas – places like Guymon, OK; Cactus, TX; Hanford, CA – and I plan to visit many more. I understand first-hand that small and very small businesses comprise the majority of the meat and poultry industry and are the foundations of rural economies across the country. They mean jobs for plant workers and a future for grocers, butchers, and farmers nationwide.

FSIS is collaborating with other USDA agencies through the “Know Your Farmer, Know Your Food” efforts to support a full range of services to small and very small operators, such as mobile slaughter facilities for small livestock and poultry producers in rural areas as well as the opportunity for State-inspected meat and poultry establishments with 25 or fewer employees to join a new Interstate Shipment Program.

With so many tools in place, it is the agency’s desire to promote policies that protect consumers without placing unnecessary burdens on businesses. We seek to utilize the expertise of our workforce at FSIS to ensure that businesses can produce the safest products possible.

Conclusion

My job and the mission of the 10,000 employees in FSIS is to protect public health through science-based policies and to give our consumers confidence that they are buying the safest

products in the world. As I noted early on, we are passionately committed first and foremost to the prevention of foodborne illness. That is our mission and the promise we make to the American public and other consumers worldwide. As has been illustrated throughout my testimony, FSIS has made a noticeable impact and has become an indispensable guardian of public safety.

As a medical doctor and a mother of two young children, I understand first-hand the devastating effects that foodborne illnesses can have on people.

Mr. Chairman, Ranking Member Farr, and Members of the Subcommittee, thank you for your help in ensuring the safety of meat, poultry, and processed egg products and for the opportunity to testify before you today. I look forward to answering your questions.