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FOOD SAFETY

Statement of Al Almanza, Deputy Under Secretary for Food Safety
Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives

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Introduction

Mr. Chairman, Ranking Member Farr, and members of the Subcommittee, my name is Al Almanza, Deputy Under Secretary for Food Safety at the U.S. Department of Agriculture (USDA). With me is Michael Young, USDA's Budget Officer. Thank you for the opportunity to discuss the status of the Agency's programs and policies.

I am pleased to appear before you today in support of the President's Fiscal Year (FY) 2017 budget request for the Food Safety and Inspection Service (FSIS), which is set at $1.030 billion. This includes an $8.5 million increase to modernize scientific approaches to food safety. With this overall funding level, I am confident that FSIS will maintain its effectiveness in its core mission of preventing foodborne illness.

FSIS is the public health agency in USDA responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled. In March, we will add fish of the order *Siluriformes* to this list of FSIS-regulated products. By law, FSIS is legally required to have inspectors present in all facilities we regulate. The USDA mark of inspection is an important part of the confidence that American consumers have in the safety of their food supply.

FSIS will always prioritize in-plant food safety inspection. The dedicated men and women of FSIS are on the front lines nationwide following procedures based on the best available scientific evidence to ensure safe and wholesome food.

When I began my FSIS career in 1978 as a slaughter inspector in Dalhart, Texas, we relied on sight, touch, and smell as a basis for our inspection system. In 1996, FSIS adopted the Hazard Analysis and Critical Control Points (HACCP) rule. This set us on a course of developing a more modern, science-based, and data-driven approach to inspection and food safety. Since June 2007, when I became Administrator, I have been responsible for making sure the Agency functions effectively, but also moves forward to implement the best new food safety inspection approaches. The investments that Congress has made in FSIS are having a positive impact on food safety that will continue to unfold in significant ways. For instance, we have continued to modernize how we do inspections, and, as a result, we have improved our ability to protect the health of the American public.

One key investment that we have been able to make thanks to Congressional support is in the Public Health Information System (PHIS). PHIS captures data in automated and useful formats. The availability of this data provides for more timely and efficient analysis of food safety inspection related trends that drive our ability to take actions that enhance our ability to protect the public health.

FSIS looks to move forward and take the next steps to modernize our science based approaches by developing and using new tools to drive results. This is a coordinated and integrated effort to improve the usefulness of data, conduct better analyses, become more proactive in reducing illnesses, improve the ability to rapidly adjust to food safety threats that do occur, and to become more effective in performing the FSIS mission.

FSIS coordinates closely with other Federal public health agencies, like the FDA and the CDC, to streamline coordination of Federal food safety analytic efforts and address cross-cutting priorities for food safety data collection, analysis, and use. Our communication with our partner agencies makes FSIS more effective and improves our responses, particularly during recalls and outbreaks. In 2011, we created the Interagency Food Safety Analytics Collaboration (IFSAC), which brings together senior leaders and technical experts on food safety attribution from these agencies. The current focus of the IFSAC is to discuss foodborne illness source attribution, which estimates the most common food sources responsible for specific foodborne illness. In

addition to the IFSAC, we have ongoing communication with our partners through the numerous cross-agency workgroups that enable food safety to be properly vetted.

In FY 2015, one of IFSAC's major successes was developing harmonized attribution estimates for *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter* for major food categories, and hosting a public meeting with over 300 participants to share those findings. These improved estimates of foodborne illness source attribution have informed efforts to prioritize food safety initiatives, interventions, and policies for reducing foodborne illnesses. These types of collaborative efforts help FSIS ensure that food safety is better informed, better targeted, and more effective.

To bolster its modernization efforts, the Agency is focusing on a theme of investment so that we can build on our ability to utilize the results of our analyses, to enhance the value of our data, and improve our sampling methods. Today, FSIS relies on scientific analysis when making our decisions. All decisions and policy changes need to be supported by sound science. Using scientific risk assessment, our Agency policies are focused on mitigating foodborne risks for consumers. For FY 2017, we are requesting $8.5 million to modernize scientific approaches to food safety. This request is composed of three parts specifically related to modernization including: Whole Genome Sequencing, Advanced Analytics, and Expanded Lab Analysis.

FSIS' commitment to modernizing scientific approaches to food safety is based on the tremendous advances being made in food safety technology. We have learned that by adopting these new and innovative advances, we will be able to strategically improve food safety. FSIS is experimenting with new ways to view and combine information to glean fresh insights from data and more effectively target potential sources/causes of illnesses. For example, the Agency has identified testing gaps for product classes and pathogens that need to be addressed.

Using an iterative approach, FSIS will begin testing to fill-in these gaps, and the Agency will learn more about contamination and pathogen prevalence for these products and pathogens. This knowledge will potentially allow FSIS to establish new standards and rules and to help better direct future efforts at determining better ways to improve food safety.

Scientific advances in Whole Genome Sequencing and lab analysis will further increase the quality and quantity of data that we can use to reduce foodborne illnesses. FSIS' Advanced Analytics initiative is improving FSIS' ability to analyze current and future data and helping our analysts in turning it into useful information.

When combined, Whole Genome Sequencing and Advanced Analytics should help us to greatly decrease illnesses by informing our enforcement activities. Stringent enforcement and better policies will provide an incentive to companies to redouble their efforts to make sure that the products they produce are safe. In turn, this should result in fewer illnesses.

Our emphasis on science and our efforts to modernize food safety have significantly contributed to the overall decline in bacterial foodborne illnesses. It is important to remember how far we've come, but our work is not done, and our inspection system modernization continues. That is what I want to highlight today as I discuss our accomplishments over the past year.

Improving the Way We Inspect

One way that the Agency is modernizing food safety is by improving the way we inspect. In 2015, we began implementation of the final rule on modernization of poultry slaughter inspection.

The implementation of the final rule requires that all poultry slaughter establishments take measures to prevent contamination, rather than addressing contamination after it occurs. Poultry facilities are required to perform their own microbiological testing in their production process to show that they are controlling enteric pathogens (e.g., *Salmonella* and *Campylobacter*).

The Agency established the optional New Poultry Inspection System (NPIS), in which poultry slaughter establishments sort their own product for quality defects before presenting it to FSIS inspectors for food safety inspections. As of February 18, 2016, 51 plants have indicated that they are interested in operating under or have transitioned to the NPIS.

The system allows for FSIS inspectors to focus less on routine quality assurance tasks that have little relationship to preventing pathogens like *Salmonella* and instead to focus more on strategies that are proven to strengthen food safety. Now, our food safety inspectors are better equipped to verify that establishments maintain effective Hazard Analysis and Critical Control Point (HACCP) systems, which is a more effective and efficient way to use our inspection resources.

Because of NPIS, a greater number of inspectors will be available to take samples for testing, check plant sanitation, verify compliance with food safety plans, and observe live birds for signs of disease or mistreatment and ensure plants are meeting all applicable regulations. As of February 6, 2016, 52 plants have indicated they are interested in operating under or have transitioned to the NPIS.

We are considering a similar approach for hog inspection. The HACCP-Based Inspection Models Program (HIMP) has shown that inspection can be more effective if modified similarly to poultry. We have collected a lot of data in these plants, and we're now in the process of analyzing that data to determine what our approach should be.

We have made other changes in how we do inspection. In FY 2015, FSIS conducted Food Safety Assessments (FSAs) and newly implemented Public Health Risk Evaluations (PHREs) to assess the design and validity of establishments' HACCP plans, Sanitation Standard Operating Procedures (SOPs), other pre-requisite programs, testing programs, e.g., generic *E. coli* written procedures, and any other programs that constitute the establishment's HACCP system. On June 1, 2015, FSIS implemented the new FSA methodology. This updated methodology creates a cost savings to the Agency and more efficiently uses the Agency's Enforcement Investigation and Analysis Officers. The average cost of an FSA before implementation of the new methodology was $5,628 compared to a cost of $2,105 with the new methodology. Using scientific assessment protocols, specially-trained personnel conducted 1,158 FSAs and PHREs in FY 2015.

In addition, PHIS is allowing us to make better use of the Public Health Regulations to focus the inspection activities of our in-plant personnel. With PHIS, we now collect data about compliance

that inspectors are verifying when they perform inspection. Before, we only knew of problems when inspection tasks found non-compliance. Now that we have more complete data, we can better assess non-compliance rates of individual regulations. That has allowed us to identify regulations where non-compliance is linked to public health outcomes.

In FY 2015, FSIS laid the groundwork for fully enforcing all HACCP validation requirements—those related to necessary in-plant data as well as those related to scientific support. The Agency informed plants that they would need to analyze their current validation methods to ensure that scientific support matches their in-plant processes, and that they needed to have at least 90 days' worth of data to show that their plants met the critical operational parameters in their processes. The new validation verification procedures, which we have begun verifying in large plants, will help ensure that establishments' HACCP plans work as intended to address food safety hazards.

To assist with this process, FSIS provided plants with *FSIS Compliance Guideline HACCP Systems Validation*, a document designed to help small and very small meat and poultry plants meet the validation requirements.

The Agency also announced training for personnel in an October notice and provided opportunities for instruction through taped training, along with live webinars. In addition, FSIS conducted outreach through webinars with industry so that all plants are able to fully understand the validation requirements.

FSIS is increasing its attention on retail because what happens at retail is the source of a couple of significant problems that we are seeing. Eighty percent of *Listeria monocytogenes* illnesses from deli meat are caused by meat that is sliced at retail establishments. To address this problem, we prepared a compliance guide on how to handle Ready-to-Eat products at retail, and now we have instituted a program in which we will have compliance investigators assessing whether and how well retail stores are following this guidance. We worked closely with industry in developing this approach.

In June 2015, we published final regulations that will require retail stores and establishments that grind beef to keep records of the sources of the beef they grind. This resulted from findings that our trace-backs during investigations ended at grocery stores, who were not keeping adequate records. This requirement will prevent such problems and allow for more effective and timely investigations.

Improving Sampling

Another focus has been improving sampling and how we use the results. The new poultry inspection system is a significant advance in this area. Last February, we fully implemented the requirement that poultry plants perform their own microbiological testing on the slaughter line to verify process control. In addition, the poultry establishments must implement plans to address enteric pathogens, like *Salmonella* and *Campylobacter*.

One of our greatest developments this year has been the new food safety pathogen reduction performance standards for chicken parts and comminuted poultry that could dramatically reduce *Salmonella* and *Campylobacter* illnesses contracted from chicken and turkey products. These performance standards are designed to reduce *Salmonella* and *Campylobacter* in ground chicken and turkey products as well as in raw chicken breasts, legs, and wings.

The performance standards are a major step in the FSIS' *Salmonella* Action Plan, which the Agency developed in 2013. FSIS' science-based risk assessment estimates that implementation of these standards could lead to an average of 50,000 averted illnesses annually from *Salmonella* and *Campylobacter*. The performance standards are designed to achieve a 30 percent reduction in illnesses from *Salmonella* and 19 percent from *Campylobacter*. FSIS chose this aggressive goal for addressing *Salmonella* because it will help achieve the Healthy People 2020 national goal of reducing human illness by 25 percent.

FSIS is also changing how we collect samples. FSIS plans to use on-going sampling throughout the year rather than infrequently sampling on 50 or more consecutive production days to assess whether establishments' processes are effectively addressing *Salmonella* and *Campylobacter* on poultry carcasses and other products derived from these carcasses.

FSIS is testing pork products to assess the need for a performance standard for parts. We are also conducting a baseline survey for beef. Our pathogen reduction standards, data collection, and sampling all reinforce a commitment to inspection that is rooted in science.

Federal Inspection of Exports and Imports

With respect to international stakeholders, the FSIS Office of International Coordination (OIC) within the Office of the Administrator serves as the Agency's point of contact to coordinate and address international issues. OIC represents FSIS in contacts with foreign governments on all FSIS regulatory matters, working in concert with other USDA and Federal agencies with international responsibilities to ensure the safe import and export of FSIS-regulated products. As part of the Agency's international coordination and outreach efforts, FSIS hosted 23 foreign government officials from 12 countries during a two- week training course on FSIS food safety and inspection regulations and procedures.

FSIS regulates all imported meat, poultry, and processed egg products intended for use as human food. Before FSIS-regulated products can enter this country, the Agency determines whether the food safety regulatory system of any country that wishes to export to the United States is equivalent to that of the United States. Once FSIS finds a foreign country's food safety system for meat, poultry, or processed egg products to be equivalent, FSIS inspects eligible products from that country at U.S. points-of-entry.

In recent years, FSIS has also improved and streamlined our Self-Reporting Tool (SRT), an equivalence questionnaire used by foreign countries to obtain or to maintain eligibility to export FSIS-inspected products to the United States. The SRT is the means by which foreign countries collect key information on their food safety systems for consideration by FSIS. In FY 2015, a total of 32 countries uploaded their responses to the core questions into PHIS. Based on its review of the SRT information, the Agency decides whether there is a prima facie basis to conclude that the country has an equivalent system. If FSIS finds that there is, it will schedule an on-site audit of the country's food safety system.

FSIS developed an algorithm to rank the auditing of foreign countries that it has determined to be equivalent and eligible to ship product to the U.S. using three data inputs: responses to scored questions from the SRT, prior audit findings, and PHIS import re-inspection data (separately assessing both process control and risk by product type and volume). The algorithm has been used in finalizing the FY 2015 and FY 2016 audit schedules. We will continue to look for opportunities to update, streamline, and enhance the effectiveness of our international program.

In FY 2015, FSIS initiated equivalence reviews of 11 countries, including three countries seeking equivalence for processed egg products. FSIS reviewed requests for reinstatement of equivalence from seven countries and reinstated Ireland's eligibility to export intact beef to the United States after beef imports from that and other European Union countries were suspended in 1998 over concerns about Bovine Spongiform Encephalopathy. One country, Lithuania, was added in September 2015, to the list of those eligible to export meat products to the United States, although the rule was not effective until October 31, 2015. In total, throughout FY 2015, 39 countries were eligible to export FSIS-regulated products to the United States.

Relative to the import process, FSIS continued efforts to enhance its efficiency in this area with a couple of important changes. First, FSIS automated activities of FSIS inspection program personnel at FSIS-regulated import establishments relative to the re-inspection of products imported into the United States. The import re-inspection activities are known as Certification and Label Verification Type of Inspection, or TOIs. Prior to CY 2015, all TOI intervals were added manually into the system, which was very time intensive. An automated program was created in FY 2015 that allowed for all intervals to be uploaded at once. The program freed up approximately 1,100 hours of time that would have been needed to update each TOI manually.

Secondly, FSIS continued efforts to automate import documentation. It has done this through development of the Partner Government Agency (PGA) Message Set, begun on April 27, 2014 at three ports of entry and with two Customs brokers. FSIS added eight more Customs brokers to the live environment and continues testing, development, and outreach efforts to stakeholders. The PGA Message Set automates the collection of information provided by the importer. These data elements are transmitted electronically when the entry is filed with Customs

and Border Protection, through the ACE and eliminates the need for importers of record or agents to submit paper forms and for FSIS inspection personnel to input the data entry.

Siluriformes, including Catfish, Implementation

Finally as noted above, as mandated by Congress, FSIS is responsible for the regulation of *Siluriformes* and *Siluriformes* products. After publishing the final rule in December 2015, we are making final arrangements to implement this new system starting March 2016.

We have established an 18-month transition period to full compliance with the new regulations. The Agency's goal for the transition period is to use that time to convey enough information so that on the first day of full implementation, September 1, 2017, there are no surprising disruptions of the inspection, importing, and exporting processes. During the transitional period, we will inspect processing-only plants and re-inspect imported product on a limited basis.

So far, we have held public educational outreach meetings in Washington, D.C. and Mississippi for industry, farmers, foreign countries, and other affiliates to learn about the program and to ask questions. Additional meetings will be held for importers and in each of FSIS ten district offices. In addition, we will be providing mandatory training for inspectors.

Conclusion

These are just some of the ways we work to achieve positive results and outcomes on critical food safety issues. We continuously track performance, modernize our approach to inspection, and apply science in addressing the problems we face. We are always looking for more efficient ways to achieve our food safety mission with the appropriated dollars we receive. I know first-hand the hard work that the dedicated men and women who make up FSIS' inspection force perform every day to ensure that we have the safest food supply in the world. Because of this work, millions of Americans can sit down at the table and enjoy safe, wholesome meals each day. Thank you for your support for our vital work as a public health agency.