

**AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION AND RELATED
AGENCIES APPROPRIATIONS FOR FISCAL
YEAR 2016**

WEDNESDAY, SEPTEMBER 16, 2015

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2:06 p.m. in room SD-192, Dirksen
Senate Office Building, Hon. Jerry Moran (chairman) presiding.
Present: Senators Moran, Daines, Merkley, and Feinstein.

FDA FOOD SUPPLY SAFETY EFFORTS

**STATEMENT OF HON. DR. STEPHEN OSTROFF, ACTING COMMIS-
SIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

ACCOMPANIED BY:

**MICHAEL TAYLOR, DEPUTY COMMISSIONER FOR FOODS AND
VETERINARY MEDICINE; FOOD AND DRUG ADMINISTRATION
WILLIAM TOOTLE, DIRECTOR, OFFICE OF BUDGET, FOOD AND
DRUG ADMIN**

OPENING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. Good afternoon to the witnesses, as well as
those in the audience. This hearing will come to order.

Today's hearing will focus on the Food and Drug Administra-
tion's (FDA's) effort to improve and maintain safety of our food sup-
ply. And I thank you, Commissioner Ostroff, for your presence here
today, Mr. Taylor and Mr. Tootle for participating in this hearing.
We are delighted for that. And, Dr. Ostroff, I appreciate the warm
working relationship that we are developing, and I appreciate the
conversations and dialogue that we have had on a number of FDA
issues over the last several months. So thank you personally and
professionally for the way that you are treating me as the new
chairman of this subcommittee.

FSMA

You note in your testimony, Commissioner, that nearly one in six
Americans fall victim to foodborne illness each year. Americans ex-
pect that the food they purchase at a grocery store or restaurant
will be safe. And the FDA is largely tasked with maintaining that
confidence. Passage of the Food Safety Modernization Act (FSMA)
in 2010 gave your agency significant new responsibilities in imple-

menting a very sweeping set of changes to the food safety laws, certainly the largest change in the last 70 years. Our hearing today is timely as it follows last week's publishing of the first two final rules for preventive controls on human and animal foods.

In delivering these new regulatory responsibilities, your private sector partners expect transparency and certainty from the FDA. And when I speak to small businesses and agricultural producers in my home State, their major concern is a Government that limits job creation and stifles innovation through burdensome regulations. I am pleased that the agency took many of the suggestions and comments from the agricultural community into account by re-proposing portions of the FSMA rules because they were unworkable for farmers. And I thank you for that.

Modernizing the FDA's regulatory controls and educating industry and consumers are at the heart of FSMA implementation, and the issuance of the preventive control rules starts the compliance process. It is vital that FDA continue its collaboration with the industry and other Federal and State agencies and issue proper regulatory guidance throughout this process.

FSMA FUNDING

I also recognize that successful implementation—this is the part that you want me to say, Mr. Commissioner. I also recognize that successful implementation does not come without a cost. And this subcommittee remains committed to investing in FSMA's implementation within the resources that are at our disposal and has done so since FSMA's enactment in 2011. I think spending in the last 5 years has increased 8 percent, something that cannot be said for many other Federal agencies. But we know that you face additional challenges and additional tasks, and we are interested in exploring how we can be more helpful. And as the process continues for appropriations this year, FSMA funding will undoubtedly play a significant role in our deliberations and in establishing priorities.

PREPARED STATEMENT

I look forward to discussing FSMA and other food safety topics with our witnesses today.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JERRY MORAN

This hearing will come to order. Good morning. Today's hearing will focus on Rural Development at the Department of Agriculture and its strategic investments in rural America. Thank you Under Secretary Mensah, Administrator Hernandez, Administrator Ridders, and Administrator McBride for being here today. Under Secretary Mensah, I enjoyed visiting with you recently in Kansas and hope you will return soon and often.

Agriculture remains one of the bright spots in our nation's economy, supporting more than 16 million jobs nationwide and forming the backbone of our rural communities. For those of us who grew up in rural areas, it is a lifestyle we cherish and hope to preserve for our children and future generations to come. Rural Development is largely tasked with maintaining and improving that quality of life. Whether it's providing loans for low-income families to own their first home, spurring economic development with grants to small businesses, or providing communities with financing to allow customers affordable utility rates, Rural Development continues to serve a significant role in the nexus between need and opportunity.

In my home state of Kansas, we determine economic development by whether or not your town has a grocery store. Many issues facing rural communities are unique

to those areas in an ever-increasing urbanized and technologically- advanced world. I look forward to discussing the Rural Development mission and other relevant topics with our witnesses today. We have a lot to cover this morning, so I will turn it over to Senator Merkley for any remarks he may wish to give.

Senator MORAN. We have a lot to cover this afternoon, and I turn now to my colleague, Senator Merkley, for any remarks that he may wish to give.

STATEMENT OF SENATOR JEFF MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chairman and thank you for holding this hearing.

I thank you, Dr. Ostroff, Mr. Taylor, Mr. Tootle, for attending.

FOOD SAFETY

The safety of our food supply is something that most Americans take for granted. For parents that enter the grocery store, for the most part, they do not have to give a second thought to whether or not the food that they are picking up for their family will make their family sick. America has and continues to have the safest food supply in the world.

But that, of course, does not mean that it is perfect, as anyone who has ever had a foodborne illness will testify to. And we need to continually work to make sure we stay ahead of a changing global marketplace. We do not think anything about eating strawberries or melons out of season because we have access to food from all over the globe. To stay ahead of this is a monumental task, and there are multiple Federal agencies involved, including the U.S. Department of Agriculture (USDA) which regulates about 20 percent of our food supply, and FDA which regulates 80 percent. Outside of the Federal Government, State agencies, private businesses, and farmers are working continually to make sure that the processes and procedures in place will make sure a domestic onion is always safe to eat, as well as an imported strawberry.

The Food Safety Modernization Act, which was signed into law in 2011, was the most sweeping update of our food safety laws in nearly 70 years. The law changed the way we look at the issue of food safety. Prior to FSMA, an outbreak would take place, and we would spend our time and resources tracking it down. Now we are working to make sure that we prevent that outbreak from occurring in the first place and giving FDA the tools and the teeth it needs to do just that. It is a better way to do business.

The law had about 50 specific deliverables, no small task for any agency. And although it took longer than many would like, FDA published two of the seven major final rules last week, and the rest will be out, as I understand, by next spring. We are at the point where the rubber meets the road, and it is going to require a new way of thinking for food inspectors who have been trained to look for an existing problem instead of working with industry to make sure those problems never materialize in the first place.

It is not always smooth sailing, and I know the folks at FDA have learned a lot about production agriculture and food processing along the way. I think most people would agree that you have done a good job working with industry to make sure that these new rules are effective while minimizing the disruption.

So, again, thank you, Mr. Chairman, for holding this hearing. It is timely and I am very interested to hear from our witnesses.

Senator MORAN. Dr. Ostroff, again, welcome and you may commence your testimony. It is a significant number of pages, and I have extended the deadline from the normal 5 minutes to 10. So please proceed.

SUMMARY STATEMENT OF DR. STEPHEN OSTROFF

Dr. OSTROFF. Thank you, Senator Moran and other members of the committee.

And I share your enthusiasm for the very warm working relationship that we have been able to develop in the last several months, and we look forward to continuing to work with you not only on food safety issues but all the other issues that FDA deals with.

So I am Steve Ostroff, the acting Commissioner of Food and Drugs, and I really very deeply appreciate the opportunity for Mike Taylor, who is sitting to my left, and me to be here to talk about the Food Safety Modernization Act, also known as FSMA.

I would also like to thank you for holding this hearing and for the committee members and their ongoing interest in this particular topic and for the strong and growing working relationship that has developed between the committee and the FDA to achieve our mutual goals of assuring the safest food supply in the world for American consumers.

FOOD SAFETY

I hope that everybody in this room knows that this is Food Safety Month, and I cannot think of a better way to celebrate than by starting the process of bringing FSMA's important new rules online as we did last week and by discussing with you today the critical next steps that must be taken to realize the goals of FSMA.

So although I have only been working at FDA for 2 years, I actually began my public health career considerably before that 30 years ago when I was working at the CDC on food safety and foodborne diseases, particularly at that time the newly recognized and deadly pathogen, E. coli O157. While working in Washington State close to Oregon, over a 2-year period, I personally interviewed every person or a member of their family in the State diagnosed with that particular infection and visited a number of them in their homes. I subsequently did the same with people with other illnesses from foodborne pathogens. So I can say, without question, that I have a very deep appreciation for the suffering and consequences of foodborne illness and have carried that perspective throughout my career as a public health practitioner and as a physician. In fact, food safety was the reason that I joined FDA in 2013 at the urging of the person sitting to my left.

Despite today having much improved technical methods to detect and investigate foodborne illness from when I started my career 30 years ago, along with some notable successes in reducing the incidence of certain pathogens, there simply remains too much foodborne illness. As you mentioned, nearly one in six Americans fall victim to foodborne illness each year. That is 48 million people. Of these, 128,000 are hospitalized and 3,000 die. This burden of

foodborne illness is shared by each and every one of us, consumers and food producers alike. The economic costs are also quite sizable. Since we know that the illnesses, hospitalizations, and deaths can be prevented, we must also, quite frankly, acknowledge that it is simply time to start preventing them.

So over here on this side, the Centers for Disease Control and Prevention's (CDC's) FoodNet data has shown that for many, many years now, the burden of illness due to the major foodborne pathogens remains essentially unchanged. As you can see, the illness burden from some pathogens goes up while for others it goes down. But looking at the poster over here on the other side of the room, in total the line remains distressingly flat. So I say to you that it is time to make that line start bending in the right direction. We believe that we now have the tool to be able to do that, and that tool is called the Food Safety Modernization Act.

FSMA

During my time at FDA, I have been thrilled to be able to participate in the process of modernizing our food safety system. This agency has stepped up to solve problems by identifying the best science and risk-based solutions that can benefit both consumers and industry. That is what we do at FDA when we are confronted by such problems. I know that Mike and his team have embedded this concept in their work to modernize the Nation's food safety system through FSMA so that it can meet the challenges of a new global era.

The enactment of FSMA was unquestionably the product of foresight and the recognition of common interests. Members of Congress on both sides of the aisle came together with consumers and with food industry leaders to enhance this ability to protect the food supply in a modern, diverse world of free-flowing commerce. FSMA stands for the proposition that the standard across the food system should be to have processes in place that we have learned work to prevent food safety problems, practices that many food safety producers are already implementing. This means having prevention-oriented standards in place that are equally applied to domestic and foreign producers, reasonable verification of compliance with those standards, and accountability for those who are unable or unwilling to comply. FSMA directs FDA to build a modern food safety system based on these central ideas.

FDA has fully embraced a dynamic, collaborative approach to implementing FSMA and is working very hard to build the new partnerships and to strengthen existing ones. This effort includes the food industry, from farmers and manufacturers to transporters and importers whose capacity and responsibility under FSMA for producing safe food is the absolute foundation of the new system. It also includes the FDA's food safety partners in other government agencies at the Federal, State, tribal, and local levels, and it also includes foreign governments, which can play an important role to help assure that the foreign supplies to the U.S. market are being produced in safe fashion. And it includes consumers and patient advocates who have been victims of foodborne illness because after all, ultimately, they are the ones that we are doing this for.

PREVENTIVE CONTROL RULES

The two final preventive control rules we issued last week are critical linchpins for building our new food safety system. They focus on implementing modern food manufacturing processes for both human and animal foods, thus ensuring the food companies are taking a 24/7 365-day a year approach and working with the FDA to prevent problems on the front end rather than waiting until a problem is recognized through identifying people with foodborne illness as you know happened in your State of Kansas earlier this year.

These rules are important in their own right, but they are only the first in a number of steps towards building a comprehensive food safety system. Three more rules will be finalized by the end of this year, those being the produce rule, foreign supplier verification process, and accredited third-party certification. Then the final tools will be issued this spring, sanitary transport and intentional adulteration. Together, these rules form the integrated holistic network for food safety called for by FSMA, all based on the principle of prevention.

Writing the rules is clearly a big step, but it is only the first step. Right now, they exist on paper. The bigger challenge ahead is implementing those rules and making them exist on the ground. We strongly believe that if we do not implement the new FSMA-mandated food safety system in the comprehensive way that Congress envisioned right from the start, that we will fail to achieve the FSMA goals of food safety, strengthen consumer confidence and a level playing field for U.S. producers. The line mentioned earlier will not bend as it should and it must go.

PREPARED STATEMENT

So I am very proud of this work and I am proud of our team. Mike Taylor alone has been a force of nature when it comes to FSMA. So please continue to work with us to achieve the level of funding that we need to accomplish on the ground what is set in statute and in rule. American consumers are depending on us and they expect this of us.

So I will just end by thanking you again for your support of FDA and for the opportunity to be here to discuss FSMA with you.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN OSTROFF

INTRODUCTION

Good morning, Chairman Moran and Members of the Subcommittee, I am Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs. I am accompanied today by Michael Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine. Thank you for the opportunity to appear before you today to discuss the Food and Drug Administration's (FDA) implementation of the FDA Food Safety Modernization Act (FSMA) and our role in ensuring food safety. I would like to thank the Subcommittee for its past investments in FDA, which have helped us meet the demands of our broad and increasingly complex mission.

I would also like to acknowledge that it was Congress' vision of a safer America that fueled the enactment of FSMA in 2011. You shared, and responded to, a widespread concern among consumers, industry, and your fellow legislators about the deadly foodborne illnesses that endanger the public health.

TODAY'S FOOD SAFETY CHALLENGE AND FDA'S CHANGING ROLE UNDER FSMA

FDA is a science-based public health regulatory Agency with mandates from Congress that span the human and animal food supply, human and animal drugs, medical devices, vaccines and other biological products, cosmetics and tobacco—products that all have profound implications for the health of consumers and the nation's economy. Like other areas of FDA's responsibility, our mandate to ensure the safety of the nation's food supply is of fundamental importance to the welfare of consumers and the industries we regulate.

FDA's responsibility for food safety dates back to 1906, when Congress first established prohibitions on the sale of adulterated food and gave FDA authority to enforce those prohibitions. FDA has used those authorities, which were largely unchanged until Congress passed FSMA, to conduct inspections and take enforcement action in response to specific cases of insanitation in food facilities, dangerous contamination of food products, and outbreaks of foodborne illness. Through these efforts and the commitment of the great majority of food producers who want to produce safe food, we have long had one of the safest food supplies in the world. And with the implementation of FSMA, our food supply will become safer.

According to estimates by the Centers for Disease Control and Prevention (CDC), every year nearly one in six Americans falls victim to foodborne illness. That's 48 million people. Of these, 128,000 are hospitalized, and 3,000 die. This burden of foodborne illness is damaging to consumers and food producers alike. And the tragedy underlying the numbers is magnified by the fact that most of these illnesses and deaths are preventable.

In the years leading up to the enactment of FSMA, a series of major illness outbreaks, contamination incidents, and product recalls—involving both domestic and imported food—focused the food industry and government on how the food safety system could work more effectively to prevent food safety problems, rather than relying so much on response after the fact. The food industry developed best practices, involving such measures as the implementation of preventive controls in food facilities, and government took incremental steps to require such controls for FDA-regulated seafood and juice processors and in meat and poultry facilities regulated by the U.S. Department of Agriculture (USDA).

Other than those incremental changes affecting a few food categories, FDA's reactive approach to food safety had changed little over the years, despite radical change in the food system. Compared to 1906, we now have a vast, complex and global food system in which changing technology, changing consumer preferences and behavior, and supply chains that extend around the world make food safety a bigger challenge than ever before. We also have seen rapid expansion in the local food movement, with many small-scale growers and processors coming into the market in response to consumer demand for locally and sustainably grown food.

All of this change and diversity in the food system is good for consumers, and creates great opportunity for American business. But it also places added pressure on our food safety system because consumers and industry alike agree: we all want food to be as safe as we can make it, and we all want to have confidence in the safety of our food, whether it comes from around the corner or from the other side of the world.

That alignment of interests is what led to the enactment of FSMA. FSMA stands for the proposition that what we have learned works to prevent food safety problems—practices that many food producers are already implementing—should be the norm across the food system. This means having prevention-oriented standards that apply equally to domestic and foreign producers, reasonable verification of compliance with those standards, and accountability for those who are unable or unwilling to comply.

FSMA directs FDA to build a modern food safety system based on these central ideas. As outlined below, this has involved developing new regulations requiring modern preventive controls in facilities producing all types of food commodities, not just a few, and establishing requirements where they haven't existed before, most notably for produce growers, food importers, and food transporters.

FSMA also directs FDA to do its food safety work in new ways, with a heavy emphasis on collaboration and partnership. This collaboration includes the food industry—from farmers and manufacturers to transporters and importers—whose capacity and responsibility under FSMA for producing safe food is the foundation of the new system. It also includes FDA's food safety partners in other government agencies at the Federal, state, tribal, and local levels, with which Congress directed FDA to build upon our history of collaboration to ensure effective and efficient implementation of FSMA. And it includes foreign governments, which can play an important role in helping to ensure that foreign suppliers to the U.S. market are producing

safe food. FDA strongly embraces this collaborative approach and is working hard to build new partnerships and strengthen existing ones.

FDA recognizes, however, that part of the change that has to happen for FSMA to succeed must happen within FDA and in how FDA conducts its food safety oversight program. To that end, and as discussed below, FDA has developed a strategy for implementing the new FSMA rules that is a fundamental departure from the past.

We believe that we will achieve high rates of compliance more quickly and efficiently by tapping into the fact that the great majority of firms we regulate want to produce safe food and want to comply. That's why our strategy takes an "educate before and while we regulate" approach, especially in the produce area, so that, through FDA guidance, outreach, and technical assistance, we can help food producers understand and accomplish what is required. It entails an approach to inspection that is aimed first at fostering and facilitating compliance, rather than at finding and penalizing regulatory violations. We will of course take swift regulatory action when needed to protect consumers when we find dangerous practices, but our focus is on prevention.

FDA is firmly committed to implementing FSMA the right way from the start. This means investing in the food safety culture change that is happening within FDA, but it also means being faithful to the comprehensive, holistic vision of food safety modernization laid out in FSMA. Congress directed FDA to build a modern food safety system, addressing food safety challenges across the spectrum of farms, manufacturers, and transporters of food, both domestic and foreign. The pieces of this system are closely interconnected. We cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers. Nor can we do the reverse, holding importers and foreign suppliers, but not domestic producers, to new requirements. We believe that if we do not have the resources necessary to implement the new FSMA-mandated food safety system in the comprehensive way Congress envisioned, from the start, we will fail to achieve the FSMA goals of food safety, strengthened consumer confidence, and a level playing field for U.S. producers.

In the remainder of this testimony, I will outline our achievements to date in developing the FSMA rules and planning for their implementation, and I will explain why the President's fiscal year 2016 budget request is so essential to the success of FSMA.

SEVEN FOUNDATIONAL FSMA RULEMAKINGS

As a first major step toward making the promise of FSMA a reality, FDA has proposed seven foundational rules, starting in January 2013. Together, they will provide a modern food safety foundation that brings to bear the most recent science, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. We have designed the rules to be both effective for food safety and workable across the great diversity of our food system.

Last week, FDA issued the first two of the final rules listed below and is on target for finalizing the remaining five in the coming months.

1. Preventive Controls for Human Food. This rule will improve the safety of manufacturing, processing, packing, and holding human food in two key ways. First, it modernizes FDA's longstanding Current Good Manufacturing Practice (CGMP) regulations. Second, it requires facilities to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, and specify actions to correct problems that arise. The rule is designed to be flexible, practical, public health protective, and consistent with industry best practices.

2. Preventive Controls for Animal Food. This rule will improve the safety of animal food, including pet food, livestock food, and raw materials and ingredients used in food for animals, by establishing general CGMPs for the first time, tailored to animal food, and establishing the same, flexible requirements for risk-based hazard analysis and preventive controls as the Preventive Controls for Human Food rule.

3. Produce Safety Standards. This rule will improve the safety of produce—fruits and vegetables that are typically consumed raw—by establishing science-based standards for growing, harvesting, packing, and holding produce on farms. The rule addresses identified routes of microbial contamination, including agricultural water, biological soil amendments of animal origin, health and hygiene of farm personnel, animals in the growing area, and equipment, tools, and buildings.

4. Foreign Supplier Verification Programs. This rule will strengthen the oversight of foods imported for U.S. consumers by requiring importers to perform risk-based activities to verify that food imported into the United States has been produced in

a manner that provides the same level of public health protection as that required of domestic food producers. This rule is the foundation for the multi-faceted new import safety system that Congress mandated to protect food safety, strengthen consumer confidence, and maintain a level playing field for U.S. food producers.

5. Accredited Third Party Certification. This rule will improve the safety of imported food and allow more efficient use of FDA resources by providing an opportunity for foreign food producers to voluntarily become certified by third-party certification bodies accredited under FDA's oversight. FDA may in turn use that certification to determine whether an importer is eligible to participate in FSMA's voluntary qualified importer program, or whether to admit certain imported food into the United States that FDA has determined poses a food safety risk. Both accreditation bodies and auditors must meet standards for legal authority, competency and capacity, impartiality/objectivity, quality assurance, and records procedures.

6. Sanitary Transportation. This rule will help ensure the safety of human and animal food during transportation by establishing requirements for shippers, carriers, and receivers of food in the U.S. Those requirements include ensuring that the design and maintenance of vehicles and equipment does not leave foods vulnerable to contamination, and taking measures during transportation to ensure that food is not handled improperly or contaminated, including using adequate temperature controls and separating food from non-food items in the same load.

7. Intentional Adulteration. This rule will help to ensure the safety and security of the food supply by requiring facilities to address vulnerable processes in their operations in order to prevent acts on food intended to cause large-scale public harm (e.g., acts of terrorism).

FDA'S COMMITMENT TO STAKEHOLDER ENGAGEMENT

Throughout the rulemaking process, outreach and stakeholder engagement have been central to developing rules that are both practical and protect the public health. FDA has worked intensively with industry stakeholders, consumers, and regulatory partners to be sure we get the rules right and to set the stage for successful implementation of the rules once they are final.

Since FSMA was enacted in 2011, FDA has been involved in approximately 600 engagements with stakeholders on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups. Even before publishing the proposed rules, FDA held public meetings to gather input on the rules' content. Since the release of the proposed rules beginning in early 2013, we have continued our commitment to outreach, engaging various industry, consumer, and other interested groups across the country and internationally.

We have heard the concerns raised by stakeholders and have adjusted the rules to include solutions to those concerns. As part of this stakeholder dialogue, FDA took the unusual step of issuing four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on revised language. Again, after the supplemental notices were issued, we engaged stakeholders to make sure our final rules would be where they needed to be. As a result of this extensive public engagement, along with our consideration of tens of thousands of formal written comments submitted to the public dockets on the rules, we are confident the rules that have been finalized and the five remaining final rules in development are flexible, practical, and consistent with industry best practices, while also being public health protective and consistent with our statutory mandate.

As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders through guidance, education, training, and technical assistance, to ensure that everyone understands and successfully plays their role in food safety. FDA believes that these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and will be a major step forward for food safety that will protect consumers into the future.

ENSURING SUCCESSFUL FSMA IMPLEMENTATION

The success of building a modernized food safety system depends on FDA and industry working together, as well as working with State and other regulatory and public health partners, after the final FSMA rules are issued. In May 2014, FDA released a FSMA Operational Strategy Document (attached as an appendix to this testimony) that focuses on how FDA intends to implement FSMA, by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community. Effective FSMA implementation will require a sea

change in how FDA, as an agency, approaches regulatory oversight of the food industry.

Inspection and compliance will be specialized, strategic, and risk-based. FDA is reshaping itself to oversee industry compliance in a manner that is strategic and based on risk. We are developing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. To effectively leverage our resources, we will use more targeted, risk-based inspection models to screen firms for food safety performance and to guide inspection priority, frequency, depth, and approach. Inspections will be systems-based, with noncompliance viewed in the context of the performance of the firm's overall food safety system and the risk to public health. In addition, FDA's inspection and compliance staffs will be trained to be specialists in food oversight, rather than covering the broad spectrum of FDA-regulated products. Members of these staffs will be teamed with FDA subject matter experts to facilitate the timely correction of problems and consistent, informed enforcement of the new FSMA regulations. Finally, FDA intends to continuously improve its inspection strategy through targeted data collection, timely analysis, and regular program evaluation.

FDA will educate before and while we regulate. Stakeholder engagement has been a cornerstone of the FSMA rulemaking process, and FDA will continue to work closely with industry and other stakeholders to achieve widespread compliance with the rules through education and technical assistance. We are currently drafting general guidance on each rule, guidance for small entities, guidance for specific commodities and sectors, and guidance on key provisions, to help industry understand their new regulatory obligations under FSMA. We are also developing a comprehensive training strategy to give food producers, focusing on small and mid-size operators, the tools they need to meet the FSMA requirements that apply to them.

For example, FDA created three alliances, or public-private partnerships, to develop training materials and create an education and technical assistance network. The Food Safety Preventive Controls Alliance and the Sprouts Safety Alliance are being coordinated by the Illinois Institute of Technology, and the Produce Safety Alliance is being coordinated by Cornell University. All three alliances bring together FDA, local and state food protection agencies, the food industry, and academia to determine what will work best to help prepare food facilities and farms to implement FSMA.

FDA has also joined with USDA's National Institute of Food and Agriculture to manage a competitive grant program that will provide food safety training, education, extension, outreach, and technical assistance to farm owners and operator, small food processors, and small fruit and vegetable merchant wholesalers. FDA plans to fund additional training programs through cooperative agreements.

Finally, FDA is building a technical assistance network to provide rapid support to food producers, providing answers to any questions they have about how to comply with the new regulations.

FDA will work closely with governmental and other stakeholder partners. A key element of our stakeholder outreach during the development of the FSMA rules has been outreach to our regulatory partners. As we transition to implementation, our partnerships with Federal, state, tribal, territorial, local, and international regulatory and public health agencies will be even more vital. We are continuing to build a National Integrated Food Safety System to ensure the quality, consistency, and effectiveness of local, state, and Federal efforts to protect the food supply. In addition, FDA will be relying heavily on state agriculture and health departments and other state and tribal agencies with food safety responsibilities, especially for the new and unique challenges of implementing the forthcoming produce safety rule on farms. We recognize the importance of harnessing the food safety commitment, knowledge of local conditions and practices, and local presence of these other regulatory entities to provide training, technical assistance, and compliance oversight in an effective manner.

Successful FSMA implementation is dependent on FDA's continued engagement with states, industry, consumer groups, and foreign partners throughout the process, to ensure that we continue to do our job in a practical, effective, and risk-based way.

HOW FSMA WILL MAKE A DIFFERENCE

The prevention model for food safety adopted by Congress in FSMA is widely recognized in the food industry and among government and academic food safety experts as the optimal approach to minimizing food safety hazards and managing problems when they do occur. FSMA also transforms FDA's oversight by focusing

us on prevention and giving us new tools to verify and ensure that prevention is happening. Two recent incidents from just this year illustrate why we need the preventive system envisioned by FSMA.

Preventive Controls in Food Facilities: Blue Bell Creamery

This case involved the presence of the unusually dangerous bacterium *Listeria monocytogenes* (Lm) in the manufacturing plants of an ice cream company. The resulting contamination of products was associated with the deaths of three people in Kansas and caused numerous illnesses in at least three other states. Under current industry best practices, manufacturers of ready-to-eat products like ice cream should have a sanitation plan and standard operating procedures that are adequate to ensure that Lm does not become entrenched in the facility, and they should conduct sampling and testing under an appropriate environmental monitoring program to verify that the presence of Lm and the potential for product contamination have been minimized.

Under the pre-FSMA food safety system, however, no such plans, procedures or monitoring were specifically required. The burden rested on FDA to find the problem, through inspection or, as in this case, via reports of product contamination and illness. Moreover, during pre-FSMA inspections, FDA could not require access to the company's production and food safety records to look for evidence of problems or for documentation that the firm was doing its food safety job appropriately. FDA could only observe what the company was doing on the days of the inspection. FDA was basically in a reactive mode, with the burden on FDA to find problems, often investigating problems after the harm was done, and being limited largely to finding evidence of legal violations suitable for taking cumbersome and time consuming court enforcement action.

Under FSMA and the preventive control rules FDA issued last week, we now have requirements for sanitation controls, environmental monitoring, and corrective actions that will apply to facilities making ready-to-eat foods such as ice cream. The preventive controls rules define the framework within which companies must put in place a food safety program that is appropriate for the hazards in their products and facilities. Companies will now be legally accountable to FDA for doing the right thing to minimize hazards like Lm, and FDA will be able not only to inspect the operations and conditions in the facility, but also to examine, on an ongoing basis, the company's records documenting the design and proper implementation of its food safety plan. With these new requirements, enhanced records access, and FSMA's administrative enforcement tools, there will be real accountability for prevention in food manufacturing facilities.

Produce Safety and Imports: Cilantro from Mexico

Mexico is a major source of a wide range of produce commodities, from staple fruits and vegetables to peppers and herbs, on which Americans depend for year-round access. FDA and our Mexican counterparts have long recognized the challenge of adequately ensuring and verifying the safety of produce in general, and the large volume of produce crossing the U.S.-Mexico border, a challenge exemplified by a series of outbreaks of illness in 2012, 2013, 2014 and 2015 caused by the parasite *Cyclospora* associated with fresh cilantro from the Puebla region of Mexico. This year's outbreak has resulted in approximately 500 confirmed cases of illness in 30 states. Like most produce safety problems, we have learned that the risk of contamination can be reduced by following recognized practices related to water quality, employee hygiene, biological soil amendments, animals in growing areas, and harvesting and packing of produce.

Before FSMA, there were no regulatory standards for such preventive practices, only voluntary guidelines. Moreover, to oversee the safety of imported produce, prior to FSMA FDA has had to rely on computer screening and on inspectors at the border physically checking a small percentage of import shipments, looking for problems. If FDA can find the problem, it can keep the problem out, but this reactive approach is widely recognized to be inadequate for the huge volume of produce and other commodities flowing into the United States from scores of countries. In the case of cilantro from Mexico, the contamination has to be prevented at its source.

Under FSMA, we will soon have prevention-oriented produce safety requirements that apply to both domestic and imported produce, including cilantro. Moreover, the Foreign Supplier Verification Programs (FSVP) requirement under FSMA will, for the first time, make importers an accountable part of the food safety system. Instead of relying primarily on FDA and its inspectors to detect and correct problems at the border, we will also be able to hold importers, and in turn their foreign suppliers, accountable for preventing the problems. This will make a big difference for food safety.

Recognizing the challenge of produce safety and the importance of FSMA's success, in 2014 we launched with our Mexican regulatory counterparts a Produce Safety Partnership. This partnership is grounded in our common interest in ensuring the safety of Mexican produce, our shared commitment to FSMA's prevention strategy, and the directive in FSMA for FDA to collaborate on food safety with foreign governments. The partnership with Mexico includes collaboration with the U.S. and Mexican produce industry so that we can coordinate with and take advantage of industry's own efforts to improve the safety of imported produce.

Such partnerships are resource intensive for FDA, but can pay big dividends when, as in the case of Mexico, we can leverage the efforts of regulatory partners who are also real food safety partners. In the current cilantro case, we are implementing jointly with Mexican authorities a program that includes continued FDA oversight at the border, but that also requires future shipments entering the U.S. from Puebla to come only from farms that have been inspected and certified by the Mexican authorities to be operating in accordance with sound food safety practices.

FDA'S FISCAL YEAR 2016 PRESIDENT'S BUDGET REQUEST FOR FOOD SAFETY

The fiscal year 2016 President's Budget includes a \$109.5 million increase in budget authority, a total of \$1.3 billion, for FSMA implementation, and a total of \$1.5 billion when accounting for all resources requested in fiscal year 2016. Full funding of the President's budget authority request is essential to maintaining momentum toward the timely implementation of FSMA in the most effective way possible. This goal could be undermined if FDA, the states and the industry are not adequately prepared to get implementation right. The three major program areas where successful implementation hinges crucially on the fiscal year 2016 budget authority request are preventive controls in food facilities, produce safety, and imports.

For preventive controls, the essential investments are for inspector training and modernization of the inspection process, as conducted both by FDA and the states, and essential guidance and technical assistance for industry so firms can know what is expected and can be supported in complying with the new requirements. This is especially crucial for small and mid-size firms. These investments are time sensitive because the preventive controls rules are the first to go into effect, and FDA is mandated by FSMA to conduct inspections in the covered food facilities at a certain frequency. If these investments are not made, industry could experience inconsistency, inefficiency, and potential disruption stemming from FDA staff who are not adequately prepared for the new system.

Produce safety is one of our most important public health priorities: we want people to consume more fresh produce, yet we continue to experience an unacceptable number of illness outbreaks from both domestic and imported produce. The top domestic produce safety investment priority in fiscal year 2016 is for states to have the capacity to be FDA's on-the-ground partner in implementing the FSMA produce safety rule that will be issued later this fall. As Congress envisioned in FSMA, our implementation strategy for produce is based on the states playing a key role in working with growers to provide education and technical assistance, and they will also be the primary provider of inspections to verify compliance. In support of this strategy, FDA and the National Association of State Departments of Agriculture (NASDA) have entered into a five-year cooperative agreement through which we are jointly planning implementation of the produce safety rule from the ground up.

The states' role is essential to success, but they cannot perform the role without resources. Investment is essential in 2016. We will have a produce safety rule on the books by this November, but, because this is a new area of regulation, we are having to build an implementation system from the ground up. Growers, especially small and mid-size operators, are already seeking education, training and technical assistance, which states simply lack the capacity to provide. States also need resources now to build the capacity they will need to carry out meaningful on-farm compliance assessments and inspections in 2016 and 2017.

Finally, for imports, FDA must have new resources to adequately implement FSMA's groundbreaking new FSVP requirement. There is no more essential element of FSMA and its successful implementation than this. FSVP is the crucial tool that FSMA provides FDA to hold importers accountable for the safety of the food they bring into the United States. They must meet this responsibility by verifying the adequacy of the food safety controls being implemented by their foreign suppliers, which means that FSVP is also the primary means of holding foreign suppliers to the same food safety standards as domestic producers, as FSMA intends. For the FSVP requirement to fulfill its purpose, FDA must have funding in fiscal year 2016 to retrain existing staff, to hire new staff with the skills needed to evaluate complex

global supply chain management systems, and to deliver education, training and technical assistance to the importers we estimate are subject to the FSVP rule.

This funding will also provide the foundation for building the multi-faceted new import safety system called for by FSMA, including more foreign inspections by FDA, expanded collaboration with foreign food safety authorities, and capacity building in countries where that will help protect food safety in the U.S. Receiving this funding is essential in fiscal year 2016 in order to align implementation of FSVP with the preventive controls and produce safety rules.

In sum, FSMA directs FDA to build a comprehensive new food safety system, based on what we know works to prevent problems—a system that is effective regardless of where food comes from. In order for the system to function properly, no key elements can be missing or lag behind. And FSMA won't achieve its purpose if the program is so inadequately funded that the system as a whole falters and fails. We want to be very clear that we cannot successfully build the new food safety system that Congress has called for without the new resources requested in the President's Budget. That is what's at stake in the fiscal year 2016 FSMA funding request.

CONCLUSION

We appreciate your strong interest in food safety, Chairman Moran, and this committee's support to date for FSMA and its effective implementation. We look forward to continue working with you to make FSMA a success. We would be happy to answer your questions.

Senator MORAN. Commissioner, thank you very much.

Let me begin just by asking. You outlined the scenario by which these rules will be announced. What was the basis for their prioritization? Is there something about these two rules that make them more difficult, easier, more significant to pursue? What do we expect in the future?

Dr. OSTROFF. Well, I will just say that they are all important. The preventive control rules are probably amongst the most important of all of these rules, and they are the ones that are expected to be implemented first. And so these had the priority to be issued. And the other ones will come shortly after that.

Senator MORAN. And the process you have been through will be the same process for the next promulgation?

Dr. OSTROFF. I will let Mike answer that. The essential answer is yes, we will issue these. The deadlines for these are set by court.

Senator MORAN. Court order.

Dr. OSTROFF. We are obligated to be able to meet all of them, and we will meet all of them. I can assure you of that.

Mr. TAYLOR. I will just add that as the Commissioner indicated, these rules are from a holistic package of standards that Congress mandated to frame this comprehensive preventive system, and so we have been through a dialogue with our stakeholders that has really addressed all of these rules because they have to fit together. And so we have to have a coherent package of regulations. So we are at the end of the process for all seven rules in terms of having gone through the notice and comment, public meetings, dialogues, and so now we are able to actually issue the rules in final. So the sequencing has something to do as well with just the capacity to get rules out the door and give a little breathing room between rules. So we are on track to get these rules out on that timeline, just as the Commissioner indicated.

Senator MORAN. Thank you very much, Mr. Taylor.

Dr. OSTROFF. So, Mr. Chairman, if I might.

Senator MORAN. You may.

Dr. OSTROFF. Mike just can make a couple comments about the implementation plan, and that may help to put some of this in context.

FSMA IMPLEMENTATION PLAN

Mr. TAYLOR. Well, again, this is a large topic, and I am sure your questions will draw it out in detail. But we are embarking on implementation and deeply cognizant of the challenges, the hundreds of thousands of facilities, and the complexity of supply chains. But we know that we can meet this challenge because we have got the alignment of stakeholders, we have done the homework, we have had the dialogue. And I think the thing that I would just provide at the Commissioner's suggestion is an overview. Some of the themes that we are pursuing undergirding the implementation that we think is crucial to success—and I think it is just crucial that we stick with these themes.

COMPLIANCE

First is this commitment, as we implement, to provide clarity through outreach and guidance about the new rules, what they require, and to be supporting of the industry in achieving what is expected through education, through technical assistance. We have said on any number of occasions that we will educate before and while we regulate, and we absolutely mean that. So that is the first theme, clarity and support for compliance.

INSPECTION

The second theme we need to do thematically, as you have indicated and the Commissioner indicated, is just fundamentally re-vamp how we conduct our inspections, how we conduct our oversight and compliance activities so that we are targeting our efforts based on risk and actively fostering and supporting voluntary compliance through frontline oversight that historically has been enforcement and reaction-oriented. Now it needs to be prevention-oriented and supporting compliance.

I always need to add the caveat. As much as we want to work with industry, if we encounter conditions where consumers are being put at risk, FSMA expects and has given us new rules to take swift action to protect consumers. But the goal has to be compliance in food safety not just enforcement as an end in itself.

PARTNERSHIPS

The third theme that I will emphasize, again picking up on what the Commissioner has said, is strengthening and expanding our partnerships with State agriculture and health departments. This is absolutely essential. We have a mandate from Congress to establish a national integrated food safety system. And we fundamentally understand that FDA cannot possibly implement this law successfully by itself. It has to work with our State and local partners.

And finally, I just reemphasize—and I think this is crucial—the commitment that I think we all need to have to this integrated, comprehensive implementation of FSMA. This system is a system. It does not work if we tease out parts or delay parts or do not inte-

grate this in a holistic way. I think the import safety provisions are particularly a crucial part of this overall system of prevention. This is how we will get a level playing field for U.S. producers. We will meet the expectations of consumers that the food that is imported into this country is as safe as food that is produced here.

So these are themes that we hope to come back to, and we want our feet held to the fire with respect to pursuing this in this way. And I think if we do this, as daunting as it may seem with the hundreds of thousands of folks we are seeking to bring into a new system, we think we can do it sticking with these themes.

Thank you, Mr. Chairman.

Senator MORAN. Mr. Taylor, thank you.

Commissioner, your charts, particularly this one—what is the explanation? What is the cycle that occurs here. You said there were ups and downs. We have had reductions and increases both. Is there a cause and effect that you could describe to me why that is with one particular pathogen?

Dr. OSTROFF. Yes. Well, it is a good question. I think if you look over here, one of the other things that I think is quite notable from this particular graph is that for many of these pathogens, that many of the reductions, the reductions being the ones that you see that are lower than one, occurred during the very early years of implementation of some new food safety activities in the late 1990s. And really if you follow that along into the 2000s, for many of these it has really been incredibly flat.

Now, I think it is important to recognize that food safety and foodborne illness is an incredibly dynamic area. We have new challenges. We have an incredibly diverse food supply. I would venture to say it is much, more diverse than what we had back in the 1990s when we started keeping some of these statistics. Increasingly the proportion that comes from overseas has grown. Sort of the locally grown phenomenon has increased over that time period. And so there are a lot of things that are challenging the food safety system and influencing the occurrence of foodborne disease. But I think the bottom line is that as these trends have changed over time, we have basically been treading water, and it is time that we no longer tread water, that we actually do things that we know will work to make these numbers look different as we go forward.

Senator MORAN. And you believe FSMA will bend that curve?

Dr. OSTROFF. I believe FSMA will bend that curve. I mean, if you look at several of the major food safety problems that we have experienced this year, including the most recent one that we have seen with the cucumbers that were imported from Mexico, the various provisions that are in FSMA are specifically designed to address the challenges that we have seen in all of those outbreaks. And so we should be able to influence not only the outbreaks that are occurring but more importantly I think the day in and day out sporadic foodborne illness which forms the bulk of this particular data.

I do also think it is important to say that while we certainly believe that all of the activities encompassed under FSMA will work to drive these numbers down, it does not absolve consumers of doing the right thing once this food gets into their kitchens because a lot can happen even if the food as it comes into the kitchens is

safe. And so it is a comprehensive approach that must be taken to assure that foodborne illness does not occur.

Senator MORAN. Let me turn now to Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

Dr. Ostroff, in your testimony, you note that FDA's strategy is taking an "educate before and while you regulate" approach. I note that you are currently working on guidance documents. This is very important considering the first two final rules are about 1,500 pages, so a substantial amount. And these guidance documents will be critical for businesses to understand and comply with the new law and they need to be timely. So folks in Oregon are asking when these documents will become available, and I will just give you a chance to answer their question.

Dr. OSTROFF. To best answer that question, I am going to turn to the person who is actually writing them.

GUIDANCE

Mr. TAYLOR. I have a large and able team back home writing them as we speak. Guidance is absolutely essential to the success of implementing these rules, and we are investing a lot of resources in that now. We have been doing that even as we have been preparing the rules themselves.

One thing I would note in the 1,500 or so pages, this is 8 and a half by 11, double spaced, but the vast majority of those pages are a preamble, are themselves guidance and explanation of what the rules actually mean and how we expect them to be applied. And so that is the first place folks should go to really get an understanding of what the codified rule language itself actually is intended to mean in practice. But that is just the first step in guidance.

So as you know, we are developing a number of guidance documents, some of which are the key foundational ones. So there will be a comprehensive guidance on the human preventive controls rule that will be almost kind of an operator's manual for those who are not yet implementing modern preventive controls like many in industry already are. For those who are not there yet, this is going to be a very helpful operating guide essentially for implementing the rules.

They will be doing a similar guidance for animal food, at least a similar guidance for both the animal food preventive controls—

Senator MERKLEY. I am just going to cut to the chase and say I am glad it is going to have this guidance. When will folks see that?

Mr. TAYLOR. These major guidances will be coming out early to mid next year, well ahead of folks' obligation to comply.

Senator MERKLEY. Great.

Mr. TAYLOR. And they will be open for comment. It will be an ongoing process of dialogue, but our best thinking will be out there in a timely way for implementation.

Senator MERKLEY. Okay, great.

FSMA AND FOREIGN SUPPLIERS

I have heard from constituents and that there are concerns that foreign businesses may not be as closely monitored as U.S. busi-

nesses, and consequently there might be greater risks from foreign products than from U.S. products. And additionally, it could put U.S. businesses at an economic disadvantage because of the clients' costs for FSMA.

In your testimony, you state that FDA cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers and vice versa. So I know you are aware of these concerns. And this all may get further discussed when the foreign supplier verification rule is finalized next month. But to the degree you can tell us now, how will the FDA adequately ensure the safety of foreign food products, and will that oversight be as rigorous as the oversight for U.S. businesses?

Dr. OSTROFF. Well, I am going to allow Mike to give you some of the details. But all I can say is that one of the fundamental tenets of FSMA is that we assure that the safety of foreign-sourced food is equivalent to domestically produced food. I think that we have that obligation to create that equity. We know that to certain degrees our tools available to us to be able to deal with imported food have been limited, but this rule, this law will not successfully work unless we can assure total equity between food that is produced overseas with food that is produced domestically. And one of the critical elements of that is that the importers that are bringing this food into the United States assure that the procedures that were in place to produce that food are equivalent to the procedures that are in place for food that is produced domestically.

Let me let Mike give you some more detail.

Mr. TAYLOR. So Congress did provide really a multifaceted toolkit for strengthening import oversight, and the Commissioner has referred to the central, really the foundational part of that which is this foreign supplier verification and requirements so that importers will now, for the very first time, have a food safety responsibility to be accountable to us for knowing their source of supply and verifying that those foreign suppliers are producing under our standards. That is a paradigm shift if we can implement it well. It is combined, though, in the design of Congress with much more overseas presence by FDA, so more foreign inspections, more partnership with foreign governments, more investment in foreign food safety capacity where that will contribute to food safety here. We think this toolkit, if implemented properly, will work to provide that equal rigor. The question is implementation. Can we make the investments needed to carry this out as intended?

FOREIGN INSPECTIONS

Senator MERKLEY. So, Mr. Taylor, you mentioned the foreign inspections, and FSMA mandated 600 inspections in 2011, with a doubling of the previous year's inspection level for the subsequent 5 years, which would mean that in fiscal year 2015, we would have about 19,000 foreign inspections. And in fact, I believe that the Department plans to only conduct about 1,200. So 19,000 under FSMA versus 1,200. This lack of foreign inspections is adding to the concern that really different standards are going to be, if you will, practiced in foreign countries because there are not enough inspections to hold them accountable. Your thoughts on that?

Mr. TAYLOR. You put your finger on a huge challenge, and that is how do we target our resources with the resources we get to implement this law effectively for food safety. So we have increased our foreign inspections from less than 300 before enactment to in the 1,200 to 1,400 range currently. And those have been very important. But they are part of the larger system. And so the inspections are not inherently preventive in the sense that the foreign supplier verification program requirement is. So in terms of priorities for implementing the import system, we have got to get 88,000 importers up to speed in terms of doing their prevention-oriented verification. And so that will be a priority for funding.

We would like to do more foreign inspections, but we also think that we can leverage the inspection activity of foreign governments through mechanisms like a systems recognition tool that we have developed where for countries who have advanced food safety systems, we want to recognize that and be able to rely, engage in a mutual reliance sort of relationship where we can rely on their inspections and not duplicate their efforts. So there are multiple elements of this.

One of the major investments we have made over the last few years with increased funding from Congress is to strengthen our foreign offices overseas, which again are going to play a vital role in us building the relationships with foreign governments, outreach to foreign industry, all those things that we can leverage our limited resources to maximize prevention activity overseas. So we would love to continue the dialogue about how we increase the inspection numbers, along with these other activities.

Dr. OSTROFF. The one thing that I do have to emphasize, though, is that part of the request that we made in fiscal year 2016 for the full amount of funding, which was \$109 million, was to be able to assure that we could carry out the requirements, especially for foreign-produced food. You know, with a number that is significantly lower than that, we will be challenged—I think that there is little question—of being able to implement the various rules that will be coming out over the coming months in the way that we envision that they need to be rolled out.

Senator MERKLEY. And I think one of those areas that the funding is impacting the United States is in filling those foreign offices. You mentioned an increase, but I believe the vacancy rate right now is 40 percent of foreign offices are vacant. Is that primarily a funding issue or a prioritization issue?

Dr. Ostroff I will say that it is expensive for us to be able to place people overseas. However, actually placing people full-time in these offices is only one of the strategies that we have been using to carry out those responsibilities. So we do cycle in people for short-term assignments to be able to assure that we can carry out the things that we need to do in those locations.

Senator MERKLEY. Thank you.

Senator MORAN. The Senator from California, Senator Feinstein.

Senator FEINSTEIN. Thank you very much, Mr. Chairman. I really appreciate the opportunity to talk with you, Commissioner, for a few moments.

I have long been interested in this, actually before my colleagues came on, and have tried to be helpful in getting more ag inspectors at our border. But that is a long time ago.

California, as you know, is a huge—it is the number one agricultural production State. Can you give me any percent or any measurement of Salmonella and Campylobacter in California-produced produce?

CALIFORNIA PRODUCE

Dr. OSTROFF. That probably is not a number that I would have off the top of my head. Given my extensive time at the CDC, I am pretty familiar with the systems that they use to collect the data, including the data that went into the FoodNet report, in which California is one of the participants in that system. And so there are data that are broken out by State for the various FoodNet sites in terms of the incidence of some of the pathogens that you see on these lists. I cannot tell you whether or not it is done on a commodity-specific basis.

Senator FEINSTEIN. Okay.

CUCUMBER SALMONELLA OUTBREAK

Now, the latest Salmonella outbreak for us is the cucumbers imported from Mexico. And I gather that is 418 illnesses across 30 States, and we have seen the most illnesses of any State, 89 illnesses, 17 hospitalizations, and one death. I am concerned that year after year, the Centers for Disease Control reports that the United States has not made progress in reducing the number of foodborne Salmonella infections that occur.

I was listening and also reading your comments how these new food safety regulations, FSMA, that you are finalizing will prevent outbreaks from happening with specific products. Take the cucumber as an example. How will you work it both at the border and in a foreign country with the farm operation in Mexico that is producing these crops?

Dr. OSTROFF. Well, I will preface my statement by saying that that particular outbreak is still under investigation, and so we do not know all of the specific details that may have led to it happening.

But having said that, I think that if you think of two of the major outbreaks that we have experienced this year, one of them being the Salmonella associated with the cucumbers and a few months earlier a parasitic pathogen, Cyclospora, that was associated with cilantro that also was imported from Mexico, you know, there are some themes about the quality and implementation of measures to prevent problems from occurring in the first place and that is at the heart of what it is that we are trying to accomplish under the produce rule. And so that produce rule establishes a number of standards that producers overseas that and producers domestically need to adhere to.

Senator FEINSTEIN. Could you give us an example of the standards?

Dr. OSTROFF. Well, you know, some of them are the water that is being used to irrigate the crops. One of them has to do with the access of animals to various locations. There is another aspect that

deals with the hygiene of the workers that are working on these particular farms. And so it is a whole variety of requirements that will be in place under the produce rule that any producer who is importing food into the United States will be expected to meet.

Mr. TAYLOR. If I just may add. The difference FSMA will make is that we have known for years what these practices are, and FDA has provided guidance, voluntary guidance, but there have been no enforceable standards, whether for domestic or foreign producers, and thus no accountability for doing the right thing. And so what FSMA does is create enforceable standards and then also verification that those standards are being met. I mean, it is that simple, but it is a profound difference from where we have been before where it was incumbent upon FDA to find and react to the problem in the absence of clear standards for prevention. It is a real game change that for cucumbers, that kind of example, will make a huge practical difference.

Senator FEINSTEIN. Right.

FSMA COORDINATION WITH USDA

Now, I gather produce is about 46 percent of foodborne illnesses, and that is under your jurisdiction, and the rest of it, meat, chicken, pork, is under USDA, if I understand that correctly. Do you coordinate in standards between the two of you or are the standards different?

Dr. OSTROFF. One of the critical requirements of being successful with FSMA is to be able to work closely with a whole variety of partners, and it is not only partners that are at the Federal level, but it is also down at the State and local level where a lot of the day in and day out work with farmers occur. And so, yes, it is very important that we work quite closely with USDA to ensure the success of what we do.

Senator FEINSTEIN. With produce—for example, I have had *Campylobacter*, and I know how serious it can be. And it was from eating not thoroughly cooked chicken. And so I asked my staff to look into it. Now, this is not your jurisdiction, but it is interesting to me that up to 40 percent of the ground chicken in markets may have *Salmonella*. And I talked to a large chicken grower in my State, and I said, what about this? And he said, well, everybody knows you have to cook chicken to 165 degrees until you eat it. I said, well, I did not know. And I do not think everybody knows.

So it raises the question of how these two agencies interact. I really think you have a good thing going in what I have read on FSMA, and I like very much how you are going about it. I worry very much about particularly chicken because chicken has become such a high item for people in terms of eating. And it does not seem to me that we make much progress year over year, year after year.

But with respect to this, what you mentioned, cilantro, cucumbers, ice cream, tuna, caramel apples, and these five outbreaks alone are almost 1,000 cases of illness and 12 deaths. Do you think that there is anything that USDA can begin to learn from FSMA? Do you think it is relevant?

Dr. OSTROFF. Again, we work very closely with USDA without question. Far be it for me to provide advice to them related to

things that we ourselves do not regulate. All I can say is that they too are working quite arduously in putting in place additional strategies to be able to address those products that are under their jurisdiction. And there are a lot of similarities to things that we are doing in FSMA to things that USDA is doing, you know, because again, from the consumers' perspective, if they end up with Salmonella, they end up with Salmonella and they are not so much interested—

Senator FEINSTEIN. That is exactly the point.

Dr. OSTROFF. [continuing] In what the source is as to what we do keep it from happening.

Senator FEINSTEIN. Right. And we have two big agencies. One handles the meat products and one handles the fresh produce products. And I have often wondered is that the best way to do it. I think you are taking action, and I am very pleased to see that.

ANTIBIOTICS IN PRODUCTS

I am also concerned about antibiotics in products and what has been happening in that human stream of consuming products that have antibiotics. Could you talk a little bit about that and what your agency is doing?

Dr. OSTROFF. Sure. As you know, this is also a very important aspect of food safety. We have had a multi-agency activity in place called NARMS (National Antimicrobial Resistance Monitoring System) that monitors not only the occurrence of various pathogens in a variety of food products, particularly meat that is sold at the retail level, but also monitors the patterns of antimicrobial resistance. We look at isolates that come from products that we regulate. USDA looks at isolates that come from products that they regulate, and CDC also incorporates information from human isolates of the same pathogens so that we can compare those patterns and look at those patterns over time.

As you know, we also have been working quite hard to be able to address the issue of antimicrobial resistance from foodborne pathogens. That is a whole other large component to their activities, especially by reducing the use of medically important antibiotics used in food-producing animals, particularly when used for growth promotion purposes. And so we have put out a number of guidances and rules specifically designed to address reductions in the use of antibiotics for those purposes. This has been a multi-year process to put those rules in place. We have done this on a voluntary basis to have all of the marketers of these antibiotics for use in food animals make labeling changes to remove growth promotion as an indication for the use of these antibiotics, and they have all voluntarily complied. The phase-in period to make those changes in the labels is to start at the end of this year. So we would look to see changes start to occur as a result of those practices.

And the other very important point of those requirements is to make sure that the use of those antibiotics for other purposes is under the direction of a veterinarian.

So both of them I think will be very helpful in terms of addressing the problem.

Senator FEINSTEIN. Thank you very much, Commissioner.

Thank you, Mr. Chairman.

Senator MORAN. You are welcome, Senator Feinstein. Thank you very much.

Just to educate myself in a more general way, let me raise a couple of topics that are a result of the questions and the testimony.

FOOD ILLNESS DEATHS

One of the things I wanted to ask about is the cause of death. You cite the CDC statistics, the 128,000 hospitalized, 3,000 die related to foodborne illness. Is there a breakdown of those deaths or hospitalization related to consumer preparation versus the food that was tainted prior to preparation? Do we know where the cause lies with the consumer versus the provider?

Dr. OSTROFF. It is not a very easy question to answer, especially when you are sometimes talking about a relatively long period between the time that the exposure may have occurred and when certainly the illness occurs and when the death occurs.

Having said that, we deal with a whole variety of different pathogens, some of which deal with items that are supposed to be cooked. Sometimes you are dealing with raw commodities like in the produce space. And so ultimately in most instances what you want to try to do—and I think what FSMA is designed to do—is to try to keep it from being there in the first place. And I think if you can successfully do that in many of these commodity areas, then you will successfully be able to have an impact in reducing these problems from occurring.

Senator MORAN. So there is a reduction that could occur in the likelihood of the problem that reduces the importance of consumer preparation of the food item.

Dr. OSTROFF. Let me just say without question that you never want to send any suggestion that consumers can become lax in the way that they handle their food because I do not think that we would want to ever send such a message. I think what we do want to do is to be able to enhance consumer confidence that the food that comes into their kitchens does not contain pathogens—

Senator MORAN. That was very artful. I will reask my question which would be there is no way—is there, Dr. Ostroff—that consumer preparation is not important regardless of what arrives in the consumer's home.

Dr. OSTROFF. You said it perfectly.

Senator MORAN. Thank you.

DOMESTIC AND IMPORTED FOODS

You indicate—well, first of all, I wanted to follow up on Senator Merkley's point about imported food versus domestic food. And he was asking for equity. An indication that you had indicated in your testimony that there is an importance to making sure that there is not an economic disadvantage to domestic producers. There is not a double standard I think is the way we would say it in Kansas. Does that double standard exist today? Is there a difference in the nature and the likelihood of foodborne illnesses from imported food versus domestic food?

Dr. OSTROFF. Since I have been answering those through the questions, I am going to turn that one over to my colleague.

Mr. TAYLOR. I think the answer is that under current law pre-FSMA, but also under FSMA, the standards are the same. I mean, Congress has made it very clear in FSMA that the same standards are to be applied. The same safety is to be achieved whether foreign or domestic.

The real difference and where there is a different challenge is in the ability to verify that those standards are being met, and we have very different challenges with imports than we do with domestic because we have an inspection force here. We can legally go into facilities. We can directly hold firms legally accountable. We have a whole set of relationships with the States who go into these facilities all the time. We can really cover that. There is no amount of foreign inspection that Congress will ever pay for us to do that would provide a comparable level of oversight through inspection overseas. And so that is why we have got this multifaceted toolkit of foreign supplier verification, more foreign inspections but very much collaborating with foreign governments. So the difference is really not so much the standards. They are the same standards. The question is how do you verify. And the imports provide a different verification and challenge than domestics.

Senator MORAN. And, Mr. Taylor, under FSMA the ability to enforce those standards is going to, in large part, rely on the certification of those who are importing food that their providers, their foreign suppliers, are in compliance.

Mr. TAYLOR. Well, that is the foundation for the new system because the U.S.-based importer is legally directly accountable to us. We can hold them legally accountable for doing that job properly. So that is where we have the direct legal handle. But then we can go over and again inspect foreign facilities. If we see a problem, we can keep that food from coming in. We can work with foreign governments again to foster good practices and to rely on their inspection activity. But, yes, the direct legal accountability for imports, in terms of private sector responsibility, is on that U.S.-based importer. So that is why that foreign supplier rule and its proper implementation is just so foundational.

Senator MORAN. What does that mean the importer is most likely to do to be able to sign that certification? What is that company going to do in a foreign country to make certain that when they attest that standards are being met, that they are actually being met?

Mr. TAYLOR. So under the regulation that we have proposed and you will see coming forward—and I am not here announcing the final content of the regulation, but I think the elements of it are evident from the proposals that we have put out and a supplemental proposal that we put out last year. But the whole idea is that—and again, this is just following the congressional mandate—the importer must have a program, a documented program where they have identified their suppliers, they have come to understand their suppliers' capabilities for food safety, they have approved their suppliers, they know the practices the supplier is undertaking, and they look at records. And under some circumstances, when justified by risk, because it is intended to be a risk-based foreign supplier verification program, we would envision the U.S.-based importer doing an audit, actually having an audit conducted

of that foreign supplier and on site onto that foreign producer. So it is having a real program that we can then audit and then, obviously, go behind that and sample product when it is coming in, go behind that and actually inspect the foreign facility, if we choose to. But it is that accountability for the importer that is the new feature that is so crucial.

Senator MORAN. The word “audit” has a different meaning than the word “inspect.” Is that true?

Mr. TAYLOR. Yes.

Senator MORAN. So when the importer is auditing, that importer is not inspecting. They would not be doing the same thing that an FDA inspector would be doing in a foreign country.

Mr. TAYLOR. Well, it is different because when you talk about inspection where we are used to going in and looking at facilities and conducting a physical exam of a physical place—the “audit” term that we are using applies to auditing the program, checking the records, being able to get confidence from examining the records and talking to the importer that they know what they are doing and they are doing the right thing. And so in that sense, it is a very records-intensive audit activity that will be at least a major component of ensuring this is being done properly.

Senator MORAN. Mr. Taylor, thank you.

I have more questions, Senator Merkley, but maybe a way to accommodate your schedule is to turn now to you, and if you are unable to stay for my final round, I would not be offended.

Senator MERKLEY. Thank you very much, Chairman.

VIBRIO INCIDENCE

I wanted to draw attention to the report that you have all displayed, the 2014 Food Safety Progress Report. For folks who are numerically challenged, you have boiled it down to happy faces, grim faces, and very unhappy faces. And the unhappiest of all is the face representing Vibrio. And over on the other chart that you have provided, you show that while every other disease has decreased since the 1998-till-now time period, there is one disease that has increased in incidence and that is Vibrio. What is the story? What particulars should we know about the challenge this disease represents?

Dr. OSTROFF. Well, Vibrio can also be a significant disease. It comes in a couple of different forms. There are several different pathogens that are encompassed under the label of Vibrio, and they are, in general, associated with seafood products. Now, I think it is important to put in context that in terms of the overall numbers, the number of illnesses associated with Vibrio was actually quite small and certainly a very small fraction of what we see in the United States from either Salmonella or Campylobacter. Some of this is associated with actual spread of Vibrio. In some instances, it was largely confined to certain areas of the country, and because of movements that occur with emerging diseases, it spread to other areas where it traditionally has not been. But it is a trend that we have been seeing particularly along the east coast.

Senator MERKLEY. I was reading an article recently about the ponds where shrimp are farmed on land in Asia and where massive amounts of antibiotics are used to control the various diseases that

are rampant in those ponds. Is that import of shrimp from these farms one of the factors contributing to the *Vibrio* expansion?

Dr. OSTROFF. I would have to get you specific information about whether or not that is contributing, but by and large, to my knowledge, most of the *Vibrio*-related illnesses are not associated specifically with imported shrimp.

[The information follows:]

While *Vibrio* related illnesses have been increasing in the United States in recent years, investigations conducted by state and local health departments have associated these infections with consumption of raw oysters and other raw forms of molluscan shellfish in the week before illness. A summary of these infections, including their recent increased recognition along the Atlantic coast, can be found on the website of the Centers for Disease Control and Prevention at www.cdc.gov/vibrio/investigations/index.html. *Vibrio* infections are most common during warmer months when the organism is more prevalent in the marine environment. Infections can be greatly minimized by consuming only thoroughly cooked molluscan shellfish.

Senator MERKLEY. Thank you.

SALMONELLA IN PEANUT BUTTER OUTBREAK

Back when we were working on this bill, a young man and his father came out from Oregon to testify. The father was a police officer. The son, when he was 3—his name is Jacob Hurley. He had experienced a life-threatening case of *Salmonella* from contaminated peanut butter. And he was one among more than 700 who were sickened by contaminated peanut products in 2009. I believe that the company involved in that was the Peanut Corporation of America.

If we look back on that particular, well-publicized incident, how would the preventive controls rule that we have just passed have made a potential significant difference in the risk of that disease?

Mr. TAYLOR. So that is an unusual case in many respects in part because of the vast scale of the damage that it did and the thousands of products that had to be recalled because this firm was selling not only peanut butter in bulk but peanut ingredients that went out into thousands of processed foods. It was a catastrophic event for the food system.

It also involved intentional conduct by the owner and operator of that facility and the well-publicized subsequent criminal prosecution and conviction.

What FSMA will do, even in that situation, is provide a much stronger basis for inspectors, when they go into facilities, to not be reliant just on looking around at the facility conditions, and pre-FSMA with no access to the records of the facility, under FSMA we will have a much stronger ability as investigators to go into facilities and make assessments of the system and to be able to detect and find records that might actually document positive analytical results such as those that occurred in this particular case that would reveal a problem that needs to be addressed. So there is always going to be that rare instance where purposeful criminal behavior happens, and there needs to be swift remedies for that.

But I think even in these cases, we will be able to be more effective in our investigatory role in assessing systems and whether this sort of practice is going on in facilities that needs to be addressed very forcefully, and FSMA gives us new rules for addressing that

sort of situation forcefully. If we identify this sort of problem through inspection, under FSMA we can actually suspend the registration of that facility and shut the facility down administratively. And that is an important tool in these sorts of extreme cases.

Senator MERKLEY. So as you note, there were exceptional circumstances, leaky roof, mold, animal contamination, so on and so forth, kind of egregious behavior regarding some known problems. But in terms of the inspections you mentioned and the ability to kind of have teeth, that matters.

PREVENTIVE CONTROL RULE AND TRACE ABILITY

But there is another element of the preventive controls rule—I believe it is in the preventive controls rules—that involves developing a tracking system for ingredients that go into processed foods. And can you just comment on whether you believe that is going to make a difference?

Mr. TAYLOR. So FDA has historically—since the Bioterrorism Act in 2001 was enacted, it has had authority to require firms to keep records of where their incoming materials came from and where their finished products have gone, one up, one down recordkeeping. FSMA adds somewhat to our authority in this area by giving us the authority to set standards for how that firm connects the dots between the incoming and the outgoing. And so that will be a step, and that is a rulemaking that is underway to put that in place.

FSMA frankly put some constraints on FDA in terms of traceability because it precludes us from requiring essentially a farm-to-table pedigree or the kind of tracing that is done by UPS and FedEx. We are precluded from requiring that sort of use of technology to improve traceability. So from our standpoint, traceability is crucial. It is how we can investigate outbreaks much more expeditiously and get to the cause of problems and solve them.

But traceability is going to have to come into the modern era fully through public-private collaboration, finding ways to harness industry innovation with the support of us and dialogue so we can be sure whatever they do helps our investigators, as well as the firms themselves. But the work to be done yet is in that area.

Senator MERKLEY. Thank you very much, Mr. Taylor, Dr. Ostroff, Mr. Tootle. I appreciate it. Thank you.

FSMA COLLABORATION

Senator MORAN. One of the things I read in your testimony that I wanted to highlight and ask you to confirm to me how serious you are about this and how confident I can be that it will remain the policy, and that is, you indicate the approach to inspection is aimed first at fostering and facilitating compliance rather than finding and penalizing regulatory violations. That is a policy, in my view, that every regulatory Federal agency should adopt. The goal is to make improvements in cooperation with the regulated. And it seems to me—and we have had this in other agencies previously in which they seem to be that was the direction they were going, but over time, the joy of penalizing became too great and the attitude of cooperation disappeared.

Is there some assurance that you mean what you say in your testimony and that it will last as part of the nature of the Food and Drug Administration as it implements and enforces FSMA?

Dr. OSTROFF. Well, all I can say is that we do believe that the approach that is expressed in FSMA, which is to work collaboratively with regulated industry—and when I say “regulated industry,” we mean from the farm to the transport into people’s homes—that we work collaboratively to encourage them and to work with them to do it right. And we know that ultimately doing it right has tremendous impact. That is not to say because, you know, you always have to—and I am sure you are quite aware. There is the carrot and the stick. And we know that the carrot is quite an effective way to promote improvements in food safety, but that does not mean that we are not going to use the stick when we need to use the stick.

Mr. TAYLOR. If I could just add why I believe this will remain the policy over time regardless of who happens to be sitting in these chairs, partly we have put it in writing. We have made this commitment to the industry and to the public, and people support this externally. But equally important for your purpose, the people at FDA embrace this wholeheartedly. The people who are at the front line in our agency are public health people. Enforcement is a tool, and that has been the culture of the agency given the statute we have had and the framework for food safety, which has basically been an enforcement-oriented statute and program. But with FSMA, we are now public health at the front line, and our front line people love that. They would much rather be getting good food safety outcomes and doing public health than trying to rack up enforcement numbers. That is just not the fundamental mentality of that cadre of people, including the young people coming into the agency. It is an extraordinarily exciting time for them and for the whole agency. So I think the future is here in terms of the culture change that is going on, and we are working in many ways to institutionalize that and embed that in the practices of the agency.

Senator MORAN. Well, would it not be fair—I mean, I recognized when I asked that question, it may sound as if you are trying to take care of business or farmers, but is the reality not that we end up with a safer food supply system when this is the attitude?

Mr. TAYLOR. We know and you know, and if you talk to the people in the food business, it is just obvious the vast majority want to produce safe food at a personal level and it is in their intense business interest to do that. And so our whole strategy is based upon that assumption. We need to work with that vast majority who want to comply, support that compliance, verify that it is happening. And for those who are not complying, we will act swiftly and we will take whatever action is needed to protect consumers, and in these extreme cases like Peanut Corporation of America, invoke punitive remedies as a deterrent. But, no, I think working with those whose interest is aligned with ours on food safety is how we will get the best public health—

Senator MORAN. If I can respond to that before Dr. Ostroff speaks, in the world I come from in Kansas, the rumor of food disease or animal-borne diseases causes dramatic consequences to

farmers, to ranchers. It does not take an actual case. Just the thought that something may be wrong. And so I am certainly not opposed to strictly strongly enforcing penalties and putting bad actors out of business because they have a huge consequence certainly to the consumer and the safety of our food supply, but for those same business men and women, those same farmers and ranchers, they cannot afford financially to have the rumor the reality that there is something wrong with what they produce.

Mr. TAYLOR. And our strategic interests are fully aligned on that.

Dr. OSTROFF. And I think you are absolutely right. We know that the ramifications from foodborne outbreaks that occurred years ago still ripple through certain commodities.

The other thing that I will say is that the approach that we will be taking under FSMA is really a fundamentally significant change to the way that we approach food safety, and it is really critical because a number of things that are encompassed in the funding request that we have made to Congress is designed to ensure that up and down the system, we can reorient the workforce to be able to implement the things that you were saying in terms of being able to work collaboratively with industry, being able to educate industry, and being able to oversee and ensure that what they are doing is up to standards takes resources. And I do not know any other way to say it. And we do know, without question, that unless we receive the total amount of the request, that something is going to have to give in some aspect of what we are doing.

Senator MORAN. You could not help yourself.

Dr. OSTROFF. I could not help myself.

Senator MORAN. And I will be happy to visit about that topic. Let me finish up a couple other items.

STATES ROLE IN FSMA IMPLEMENTATION

When it comes to the State of Kansas, the State of Oregon, the State of California, what will the role be for those States as a result of FSMA and its implementation? What happens different at the Kansas Department of Health and Environment?

Dr. OSTROFF. Well, the approaches that are being taken at the Federal level—those same types of changes will also occur at the State level. The States and localities are really very critical partners in implementing FSMA as it is designed to be implemented. They are our front line eyes and ears. They carry a lot of the workload in not only working with their regulated industries at the State and local level, but particularly in certain areas. And the one that comes to mind most is the produce rule. We will look very much towards working with the States to be able to provide the type of front line support to all of the farmers within their States to be able to appropriately implement the new requirements for FSMA. And so they are really critical to the success of this endeavor.

ANIMAL FEED RULE

Senator MORAN. Let me ask one question related to the animal feed rule and contract farmers. Doctor, you indicated—Commissioner, you indicated to me that in advance of this hearing, that what I was going to hear from the folks out there in that world

would be all requests to make sure that Congress appropriated sufficient funds to implement FSMA, and that you had worked your way through many of the challenges and had a lot of input from stakeholders, as you described. And I appreciate that, and it seems to me that that is in large part the reality.

One area that I have heard concern about is the definition of what a farm or farmer is. And you are shaking your head and so maybe I do not need to describe the issue. Is there something afoot that I ought to know about the direction that you are going? What I have heard, that there is concern from farmers who have no involvement in anything other than raising the livestock, the animal, that FSMA will affect their operations as well when all the processing and everything occurs downstream. And in fact, the feed, most importantly, is not grown or provided by them. It is provided by upstream buyers of those they have contracted with. This is an issue—have I described it adequately. You were once smiling. Now you are frowning.

Dr. OSTROFF. Well, no, because the specific way that a farmer is defined is really critical to certain parts of these rules, not only the preventive controls but also to the produce rule. And so we have worked quite closely with those that will be impacted by this rule to make sure we can get it about as right as we possibly can.

I will ask Mike because I know he has been immersed in this particular issue for the last several years.

Mr. TAYLOR. I do know the issue very well, and the fact that there is presumably still some folks who have some concerns just shows that there is an exception to every rule—but stakeholder support for the rules.

But I think that what you are talking about is the situation where there are vertically integrated poultry operations where a Perdue or a Tyson will own the chickens. They will manufacture and own the feed. They will provide it to contract growers who own—

Senator MORAN. The growers only grow.

Mr. TAYLOR. The growers only grow.

The growers—if they have a concern that they are affected by this, I have not heard that and I do need to hear that. The affected party is the operator of that feed mill, that is not being managed on or by a farm operation but rather by this big vertically integrated poultry enterprise. That feed mill is subject to the animal feed preventive controls rule. The requirement is very practical and risk-based and so do not address issues that do not need to be addressed in terms of ensuring the safety of animal feed. But those feed mills are subject to preventive controls. If the poultry operator or any farmer—and this is the common practice for poultry—is growing or processing their own feed on their farm in their feed mill for their animals, that is part of the farm operation and would not be subject to the preventive controls rules.

So I would be happy to engage whoever has the concern and connect them with our Center for Veterinary Medicine and work through whatever the question is. But that is basically the way the rule—

Senator MORAN. You answered the question better than I asked it, and I think that is the assurance that they were having to hear.

Mr. TAYLOR. Okay. Well, again, I am happy to talk to them if that would help.

BUDGET REQUEST

Senator MORAN. Let me talk just a moment about the appropriations process. And I indicated in my opening statement this will continue to be a priority certainly of mine and I think of this subcommittee. And you mentioned specifically the amount of money that the President's budget requests and our ability to meet that at this point has not occurred. But we worked hard to put more money into FSMA implementation as we prioritize within the dollars that we have within our jurisdiction. And if those dollar amounts change, we are interested in reviewing and reprioritizing based upon what the needs are of FDA and others to try to make certain we make the right priority decisions.

But let me ask a couple of things about how the money has been spent in the past. As I indicated in my opening statement, the number, I believe, is an 8-percent increase over the last 5 years for implementation of FSMA at FDA. Mr. Tootle, am I saying that correctly?

Mr. TOOTLE. I think it is 4 percent, sir.

Senator MORAN. Of course, you do.

FSMA SPENDING

Senator MORAN. Well, let me ask how that money has been spent in implementation and how has it been allocated. Is it across food safety inspections, foodborne disease surveillance, detection? How have you decided how to spend that money over the past 5 years? And I will consult with my expert.

Dr. OSTROFF. So the total amount since 2010 that has been allocated specifically for FSMA—I believe the number is approximately \$162 million over that time period. It has been used in a whole variety of ways, but as you probably recognize, there has been a tremendous effort on our part to be able to appropriately lay the groundwork to get these rules to a place where those rules are both implementable and will work. And that is no mean task. As you know, we have had tremendous numbers of outreach activities to the various stakeholder groups. There have been somewhere in the range of 600 or so meetings that have occurred, either public meetings, interactions with regulated industries, various trade associations. As you know, we have walked facilities and farms from one coast to the other. There has been a significant effort to actually do all the writing that it takes to get these rules to the place where they were. As you know, we issued a number of supplemental rules. And so that has heavily contributed to a lot of the resources that we have used to get to the point where we can actually get to where we are now, which is to start implementing.

Mr. TAYLOR. In addition, there are a number of programmatic and capacity investments that we have made that I think are very significant as well. Some of it includes technical staffing, increasing technical staffing at the agency, so we can support the industry, our State partners, our own inspectors as they implement this. So this is at our Center for Food Safety and Applied Nutrition principally. We have doubled the investment in the States to close to

\$50 million over the last few years. We have been able with the resources we got, including these increases, to meet the FSMA mandate for high-risk inspections, the frequency mandate, and exceed that and do that earlier than expected. We think that has been an important part of getting ourselves in a position to succeed under FSMA.

And then the import area has been an area of investment. We have significantly increased the number of inspections, as I mentioned. We have expanded the foreign offices, things we have talked about. So there have been some significant programmatic investments in capacity for ourselves and the States to be ready to implement FSMA. It is part of an ongoing sort of buildup so we can succeed going forward.

Senator MORAN. Thank you, Mr. Taylor.

Mr. Tootle, it is apparently one of those circumstances in which both are right.

The desired outcome has been achieved. Food has increased by 8 percent, FSMA by 4.

REPRIORITIZING FUNDING

I think this is my final question. Is there any opportunities—let me ask that differently because there has to be. As you implement FSMA, are there opportunities for reprioritizing existing spending that that spending is no longer necessary because you are headed down a different path than the way the FDA operated in the past? So are there any savings to occur as a result of the implementation of FSMA?

Mr. TAYLOR. My Commissioner is looking at me, so I will say something.

Dr. OSTROFF. Because my short answer would be no.

Mr. TAYLOR. I think I am going give yes. That is a no because I want to try to explain, though. If you look at the overall funding of the foods program, about three-quarters of it pre-FSMA goes into the field based activities that relate to food safety but doing it the old way. What we are talking about is adding frankly incrementally to that base resource so we can reorient, redeploy all of that resource to doing food safety in the way envisioned by FSMA.

Senator MORAN. It is not the best answer.

Mr. TAYLOR. I wanted to get credit for the fact that we are not just continuing to do all the old stuff and then add on the new thing.

Senator MORAN. That is the nature of my question.

Mr. TAYLOR. Yes, sir. And the answer is we are redeploying but it does not mean we can stop spending the money that is needed to support that workforce. We have to, in fact, invest in it so it can work in this modern prevention-oriented way in a much more sophisticated regulatory framework. So, yes. So it is redeployment as opposed to adding on resources on top of resources that are still deployed doing the old thing.

Senator MORAN. That is what I want to hear. And since you, Dr. Ostroff, wanted to answer no, I will give you the opportunity to say yes.

Is the reality not, is the truth not that we can now—as we do things differently, you redeploy assets, resources that were directed in the old way of doing business to the new way of doing business?

Dr. OSTROFF. So this is not going to require fewer people to be successful. It is just going to require that those people do things differently than they have been doing them, but the people that we need to be successful for FSMA will not—you know, we are not going to have people go away. And in point of fact, given the various responsibilities that we have under these rules, we need every single one of those people to be successful in implementing this. So from the standpoint of what we have been doing with our field force and what we have been doing with our laboratories, those responsibilities do not disappear under FSMA.

Senator MORAN. Dr. Ostroff, thank you for your testimony. Mr. Taylor, thank you for being here. Mr. Tootle. Anything you would like to make certain that is included in the record before we close this hearing?

Dr. OSTROFF. Well, I will just close by saying I am the eternal optimist. The request that we made for this fiscal year for FSMA implementation from my perspective is absolutely critical to its success. And to make this have its maximal impact, which we hope that it will have to change some of these graphs that you see here on the right and the left, every component of that request is vitally important to the success of this endeavor. And so we will have some incredibly difficult choices to make if we cannot get that particular request. And so I recognize that you have been an ardent supporter of the success of FSMA, and we certainly are totally appreciative of the efforts that you have made to this point, and we are very, very appreciative of the resources that did show up in the subcommittee's and full appropriation for FSMA implementation. All I can say is that there will be some significant shortfalls that will result with that particular number, which will make it very challenging for us to be able to put in place right from the get-go what we need to do to be successful in this endeavor.

ADDITIONAL COMMITTEE QUESTIONS

Senator MORAN. Doctor, thank you very much. I appreciate your testimony. Thank you for being here. I appreciate the presence of my colleagues. And for members of the subcommittee, either those that were here or who were not, any questions that they would like to submit for the record should be turned into the subcommittee staff within 1 week, which is Wednesday, September the 23rd, and we would appreciate having a response back from FDA within 4 weeks subsequent to that point in time.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

PRODUCE SAFETY

Question. Please provide a food safety risk rationale why FDA concluded that Produce Safety provides adequate regulatory oversight for on-farm packinghouses that pack any amount of produce not grown on the same farm, and “secondary activities farms” that are majority owned by the primary production farm(s) that pro-

vide a majority of the produce packed, but an off-farm packinghouse that performs the same activities on the same commodities requires the added complexity of the Preventive Controls rule if more than a majority of fresh produce packed is not grown by the packinghouse majority owner(s).

Answer. Produce packing houses that fall under the new farm definition and pack covered produce would be covered by the forthcoming produce safety rule. Produce packing houses that do not fall under the new farm definition would be facilities covered by the preventive controls for human food rule. We recognize that this means that establishments performing basically the same activities will be governed by different regulatory regimes. We are limited by our statutory authority. FSMA sets up a dichotomy, where farms packing and holding covered produce are subject to the produce safety rule, with its regulatory structure, and facilities required to register are subject to the preventive controls for human food rule, with its regulatory structure. We have expanded the farm definition as far as we think we can, while still reflecting what a farm is in the real world.

However, we expect that the specific steps necessary to ensure the safety of produce would generally be the same for on-farm and off-farm packing houses. For example, the preventive controls rule allows a packing house, for produce covered by the produce rule, to comply with the applicable requirements for packing and holding under the produce rule rather than to comply with the Current Good Manufacturing Practice (CGMP) requirements. In addition, although an off-farm packing facility would be required to establish and implement a food safety plan and establish preventive controls for food safety management components, we expect that, in general, off-farm packing houses can look toward the produce safety rule for guidance as to what to include. We expect that an off-farm packing facility's food safety plan would focus on a few key preventive controls with counterparts in the proposed produce safety rule. For example, we expect that the food safety plan for an off-farm packing facility would include preventive controls such as maintaining and monitoring the temperature of water used during packing. We also expect that an off-farm packing facility would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces. These preventive controls have counterparts in the proposed produce safety rule.

ANIMAL FEED

Question. In regard to the Rule for Preventive Controls for Animal Feed, the FDA has indicated it did not intend to regulate farmers/growers of animals. However, it appears that the Animal Feed rule will cover a significant number of contract farming operations, even though the owners of the animals have 100 percent control over feed manufacturing.

How many feed mills and/or farm operations do you expect this rule to cover?

Answer. The Preventive Controls for Animal Food (PCAF) rule applies to all facilities that are required to register with FDA under section 415 of the FD&C Act because they manufacture, process, pack, or hold animal food for consumption in the US. Farms are not required to register and therefore are not covered by the PCAF rule. Whether a feed mill is covered by the PCAF rule depends in part on whether it is considered part of a farm. FDA's Food Facility Registration database tracks the number of registered facilities. As of August 9, 2015, there were 5,919 domestic animal food facilities registered and 9,804 domestic facilities that were registered as human and animal food facilities. The 5,919 domestic animal food facilities are covered and likely a portion of the facilities that are registered to produce both human and animal food. The facilities that produce both human and animal food may choose to follow human food current good manufacturing practice and preventive control requirements throughout their facility instead of following the requirements of the PCAF rule for their animal food (as long as any hazards for the animal food are addressed). Within the total of domestic registered facilities, there may be some facilities that are subject to one or more exemptions from the PCAF rule or are subject to modified requirements.

Question. Are you going to prioritize regulatory oversight on the animal food rule, and does the agency plan provide guidance to clarify this issue?

Answer. Full funding as requested in the fiscal year 2016 President's Budget is necessary for FDA to implement all of the FSMA rules, including PCAF, in a holistic, risk-based way. FDA has been developing implementation plans for the PCAF rule, and we are also currently working on development of regulator training and guidance documents. FDA is planning guidance documents to help industry comply with the requirements of the PCAF rule. The first guidance will be for implementa-

tion of the Current Good Manufacturing Practices provisions, closely followed by a guidance document on human food by-products for use as animal food. FDA will make available another guidance document that will address the hazards associated with different foods and how to apply the preventive controls requirements. There will also be a Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

IMPORT SAFETY

Question. How many foreign manufacturing facilities are there and what are the top countries that export to the United States?

Answer. There are approximately 118,104 registered foreign food facilities. The following table provides the top ten countries that export to the United States in order from most to least food import lines. The top two countries are Mexico and Canada.

Top Ten Countries for Food* Imports - FY 2015 (Oct 1, '14 - Sep 30, '15)			
Row Labels	Total Lines	Food Lines	% of Food Lines
Mexico	7,571,115	3,726,626	49.2%
Canada	5,103,980	2,992,169	58.6%
Italy	850,241	478,524	56.3%
Japan	690,756	395,139	57.2%
France	947,631	388,648	41.0%
China	6,430,589	283,680	4.4%
India	439,934	220,362	50.1%
United Kingdom	577,016	175,316	30.4%
Korea (the Republic)	324,230	166,355	51.3%
Thailand	437,755	156,707	35.8%
*Food Lines include: Human Food, Infant Food, Dietary Supplements, Color & Food Additives			

Question. What is the process to inspect/approve products from these facilities? How does FDA interact with foreign governments, and their inspection regimes?

Answer. The process of inspecting foreign food facilities begins with the Center for Food Safety and Applied Nutrition (CFSAN), which identifies foreign facilities for FDA inspection based on risk factors including whether or not they produce high-risk commodities or employ high-risk practices in the manufacturing process. Specific foreign countries are not targeted for inspection unless there are specific disasters, events, or country-wide practices associated with production that may pose a unique risk. FDA foreign food facility inspections are conducted by dedicated foreign food inspection cadre/investigators, domestic food inspection investigator volunteers, and foreign office investigators based overseas. The Office of Regulatory Affairs (ORA) plans and conducts foreign inspections for U.S.-based investigators, whereas inspections conducted by overseas-based investigators are planned by the relevant FDA foreign office (FDA has investigators based overseas within FDA's foreign offices in China, India, and Latin America). Specific foreign inspections trips are planned based on firm location, availability, reason for inspection, and commodity. After the completion of a foreign inspection, FDA may take steps such as placing a firm's product on Import Alert, based on observed and documented violations. FDA regularly interacts with foreign governments and their inspection/regulatory regimes. When FDA intends to conduct inspections of facilities in foreign countries, CFSAN informs the foreign government regulatory authorities and invites the foreign authorities to observe the FDA inspections. ORA or an FDA foreign office provides the foreign regulatory authority with information that includes the timeframe of the inspections, the list of firms to be inspected, and final itineraries if desired. Foreign regulatory authorities often accept invitations to observe FDA inspections, which provide learning experiences for the foreign authorities.

FDA's India Office and the Indian drug regulatory authority will collect data pertaining to either regulatory agency's observations of the other's inspections in the future. This data-gathering exercise will facilitate data analyses for developing a better understanding of current inspectional and regulatory practices of each regulatory agency and developing strategies to better cooperate on matters of mutual regulatory concern.

The Latin America Office has conducted foreign inspections and environmental assessments accompanied by foreign counterparts. These activities are conducted in an effort to leverage our combined resources, ensure the application of standards, and increase regulatory capacity. During accompanied inspections, the foreign regulatory authority and FDA conduct concurrent inspections of an establishment. During the inspections, there is constant communication and discussion between the two authorities. We have seen certain foreign authorities take regulatory action on the spot when conditions that pose a serious risk to the health of consumers are encountered. Foreign regulatory authorities have taken their own samples and have ordered the destruction of potentially contaminated products. The same situation occurs when a collaborative/joint environmental assessment in response to a foodborne illness outbreak or a food contamination event is performed. If FDA subject matter experts find a major violation, foreign counterparts may be able to take immediate regulatory actions. They may also conduct a follow-up inspection at the firm to ensure that corrective actions were implemented.

The China, India and Latin America Offices have shared information, as appropriate, with regulatory counterpart organizations in China, India and Mexico after inspections in those countries. This has resulted in actions by the regulatory counterpart organizations based on violations observed by FDA.

In 2014, FDA signed the following arrangements with Chinese, Indian, and Mexican regulatory authorities that affect FDA's interactions with those authorities regarding food safety inspections:

- Two Implementing Arrangements with Chinese regulatory counterparts that outline cooperation regarding inspections of food and drug facilities in each other's countries. Since the signing of the two Implementing Arrangements, cooperation and the exchange of regulatory enforcement information have increased. The number of FDA inspections that Chinese regulatory counterparts have observed has also increased. Additionally, FDA received visas for new inspectional staff whose visas had been previously delayed.
- A Memorandum of Understanding (MOU) with Indian regulatory authorities that will improve cooperative activities in the area of food safety. The India Office also conducts quarterly meetings with Export Inspection Council (EIC) to advance the implementation of the MOU and share information for regulatory and/or risk-based decisionmaking.
- A Statement of Intent with Mexican authorities to develop and implement a Produce Safety Partnership that aims to achieve mutual confidence in one another's produce safety systems. Under the Statement of Intent, five working groups were established. Two of these working groups have focused on inspections: Exchange of Information and Training of Auditors/Inspectors and Outbreak Response. These two working groups have conducted thorough, in-depth discussions that have led to enhanced interaction when FDA conducts inspections in Mexico.

FDA's China, India, and Latin America Offices have also engaged in technical workshops with our foreign regulatory counterparts to strengthen the regulatory understanding and capabilities of inspectorates abroad.

- FDA's China Office has engaged with Chinese regulatory authorities regarding data integrity and compliance in the area of Low-Acid Canned Foods (LACF) by holding classroom training on FDA's regulations and inspection training at a facility. A total of 30 Chinese inspectors attended, including one inspector from each of the Chinese provinces that export LACF products to the United States as well as 10 inspectors and several managers from various Guangdong authorities' offices where the training was held.
- FDA's India Office partners with Indian regulators to train them on food- and drug-related issues and inspectional techniques, good manufacturing practices, and the detection of data integrity issues.
- The Latin America Office has facilitated participation by foreign regulatory officials/inspectors in courses provided by FDA's Office of Regulatory Affairs training component (ORA-U), thereby helping enhance the knowledge, skills and capabilities of foreign regulators, as well as helping them better understand the U.S. food safety system.
- FDA's Europe Office does not include investigators among its staff, yet it facilitates FDA inspections of facilities in Europe by cultivating and maintaining re-

relationships with regulatory counterparts in Europe and working with U.S. governmental agencies in-country with complementary missions, e.g., the U. S. Department of Agriculture's Foreign Agricultural Service.

In addition, FDA's overseas offices contribute to FDA's international inspections by analyzing reports/audits by foreign regulatory counterparts to aid in facility selection.

Question. How do you propose to support and build upon these efforts to open FDA offices in foreign countries? Could you provide more detail on the types of activities these offices should be carrying out, and what benchmarks we might use to measure the success of these activities?

Answer. Since 2009, FDA has operated foreign posts strategically located around the globe, including in China, India, Mexico, Belgium, United Kingdom, Costa Rica and Chile. The India and China posts have significant numbers of investigators in the foods/feeds and medical areas. The goals of the foreign posts include:

- Building FDA knowledge around the foreign competent authority's (CA's) capacity, the role industry(ies) plays in the country, and the dynamics between these two.
- Strengthening FDA linkages with CAs and public and private stakeholders for increased and more timely information and collaborative approaches to tackling issues of concern to FDA.
- Increasing awareness of foreign governments, industry and others about FDA regulatory requirements, as well as new legislation such as the FDA Food Safety Modernization Act and the Food and Drug Administration Safety and Innovation Act.
- Conducting FDA inspections and investigations in country, including for-cause and surveillance inspections. FDA encourages CAs to observe our foreign inspections, which provide learning opportunities for foreign regulators.

Measuring impact is a complex process(es). The Office of International Programs is developing metrics to benchmark and better measure success of these types of activities performed at FDA foreign posts. These could include the number of FDA inspections conducted in the country or region, but optimally would measure the impact of FDA inspections, workshops and other collaborative activities on the rate of violative products from the country or region and capacity of foreign regulators conducting inspectional work.

Question. What, specifically, are obstacles these offices face in monitoring foreign food production and foreign food safety systems?

Answer. The food safety systems in some countries are complex and involve multiple regulatory authorities at the central and regional/state/local levels. Responsibility for regulatory oversight may not be well-defined or able to be measured. Implementation of food safety standards and enforcement activities may vary significantly by region. Thus it can be challenging to monitor and, more importantly, understand the regulatory systems, regulatory capacity and national policy dynamics.

Language and cultural contexts are also challenges in building FDA knowledge around foreign food production and food safety systems, particularly given the difficulty of translating often nuanced policies written in a foreign language.

Question. What types of authorities and resources will those offices need in order to be effective?

Answer. FDA is currently evaluating if additional authorities and/or resources will be needed in fiscal year 2017.

QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

Question. How has FDA worked with NIFA at USDA on outreach and training for FSMA? Do you expect that small local organizations will be able to compete for FSMA training dollars, both at USDA and FDA?

Answer. FDA and USDA's National Institute of Food and Agriculture (NIFA) have joined in a collaborative partnership to administer and manage the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program using competitive grants, with the goal of providing training and technical assistance to owners and operators of small and medium-sized farms, beginning farmers, socially-disadvantaged farmers, small processors, and/or small fresh fruit and vegetable merchant wholesalers, as mandated in Section 209 of FSMA. Community-based organizations (CBOs) are among the eligible entities to receive grant funding, and the requests for applications have specified that this program will provide significant opportunities for funding through subcontracts and for partnerships with eligible stakeholder groups who work directly with the target audiences.

The joint program will first award competitive grant funds that enable an awardee to establish a National Coordination Center (NCC) for Food Safety Training, Education, Extension, Outreach, and Technical Assistance and then award grants for the establishment of four Regional Centers (RCs) across the country. The RCs will work with local communities to ensure that the training teams include representatives from non-governmental organizations, CBOs, cooperative extension services, food hubs, local farm cooperatives, and other entities that can address the specific needs of the communities they serve.

FDA issued a request for grant applications for the establishment of the NCC on December 31, 2014, which closed on March 16, 2015.¹ FDA has awarded the International Food Protection Training Institute a grant of up to \$600,000 over 3 years to establish the NCC.

NIFA published a request for grant applications for the establishment of two of the Regional Centers—one in the Southern Region and one in the Western Region—on May 18, 2015, which closed on June 29, 2015.² NIFA has awarded more than \$2 million in grants to establish these RCs. The University of Florida in Gainesville will establish the Southern Regional Center, with Oregon State University in Corvallis charged with establishing the Western Regional Center.

Additionally, on August 27, 2015, FDA published a request for grant applications for the establishment of the other two Regional Centers, one in the Northeast Region and one in the North Central Region.³ This request is open through November 2, 2015, and eligible applicants can be found at the link provided.

Question. In your statement, you say that FDA plans to fund additional training programs through cooperative agreements. Please provide more detailed information.

Answer. FDA-funded cooperative agreements encompass a range of actions to support implementation of the FSMA rules.

- The agency has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan implementation of the forthcoming Produce Safety rule.

- Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation effort is actively participating in the development of these practices.

- NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.

- To accommodate alternate approaches to FSMA readiness, the FDA plans to fund development of specific training programs through cooperative agreements. The agency's goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA. These training programs would include providing an awareness of the underlying reasons for the new standards and would ensure that training addresses the unique needs of the target audiences.

Specifically, cooperative agreements are planned to support curricula development and dissemination among two such communities: local food producers, including those engaged in direct marketing, and tribes.

- The agency plans to allocate fiscal year 2016 funds for the development of training curricula and delivery, in addition to education and outreach, with a focus on small and mid-size businesses involved in local food production, including those that engage in sustainable and organic farming. Eligible entities will include community-based organizations and other grassroots organizations that work directly with the intended audience.

- The FDA anticipates funding a similar cooperative agreement for the development of training curricula and dissemination in tribal communities. Tribal governments and community-based and/or non-governmental organizations will be among those eligible to receive the funding.

- The FDA will be involved in facilitating communications between the Alliances and the participants in the new cooperative agreements to maximize use of materials that are already developed, when appropriate.

Question. FDA officials have stated that if FDA doesn't get its full budget request, all of the increase provided will go toward the two rules just published, and produce safety will have to wait. Why shelve one very important item completely instead of taking a more pro-rata approach?

¹ <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-15-003.html>

² http://nifa.usda.gov/sites/default/files/rfa/fy2015%20FSMA%20RFA_to%20post.pdf

³ <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-16-005.html>

Answer. The fiscal year 2016 President's Budget requested for each of its six proposed FSMA funding categories is the minimum amount FDA needs to effectively make progress on the critical implementation tasks in each category. All of the funding categories are vital to achieving FSMA's goals of a modern, preventive food safety system that protects consumers, strengthens public confidence, and reduces cost to industry from food safety problems. A significant shortfall of funding in these categories will unavoidably disrupt and delay FDA's plans for implementation of FSMA.

The urgency of receiving full funding in fiscal year 2016 is that it is the year that both preventive controls regulations are scheduled to become effective and, thus, the last year to make investments that are crucial to orderly, effective, and timely implementation. In FDA's own estimate of funding need, enactment of the President's request for a budget authority increase of \$109.5 million, for a total of \$1.3 billion in Budget Authority, and total Program Level of \$1.5 billion when accounting for all requested resources, would make it possible for FDA to move forward in 2016 toward successful implementation of FSMA.

If FDA were to receive less than full funding requested in the President's Budget for FSMA implementation in fiscal year 2016, FDA would focus on the highest priority activities. FDA's prioritization of activities aligns with the President's Budget policies related to FSMA. These priorities were decided with the full knowledge of the compliance implementation dates for the FSMA regulations identified.

FDA would prioritize its focus on the FDA and state inspection modernization, training and industry assistance investments needed to implement preventive controls in all food facilities effectively and efficiently.

FDA will make the best possible use of any available resources, but failing to make the proposed investments in any of these priority areas will force decisions to delay implementation of key elements of the new food safety system.

Question. Will your revised proposal for irrigation standards for fresh cured onions remain when the final rule is published?

Answer. As mentioned in the originally proposed produce safety rule (2013), we proposed to adopt an approach focusing on the likelihood of contamination of produce posed by the agricultural practices applied to the crop. We conducted a qualitative assessment of risk (QAR) of hazards related to produce production and harvesting. The draft QAR indicated that all produce commodities are potentially subject to similar microbiological hazard pathways: commodities can potentially become contaminated from, for example, direct exposure to contaminated water or soil amendments. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is otherwise relatively low. Therefore, we proposed to adopt a regulatory approach for minimizing the risks associated with those hazards and, as appropriate, provided flexibility for the use of alternative measures that would provide the same level of public health protection as the proposed standard.

We received many initial comments and questions on this approach and on the topic of agricultural water, some of which were submitted by the onion industry. We are considering these comments as we continue to develop our thinking surrounding food safety on the farm. With regard to your question on the proposal for irrigation standards and onions, we also heard many concerns regarding the treatment of onions under the rule during our listening sessions and meetings with growers. The proposed rule provides a staggered compliance approach which allows an additional two-year compliance period for farms to comply with certain agricultural water standards.

We have also evaluated the comments received to the docket for the Supplemental Notice and are carefully considering them in developing final requirements. Our goal is to determine an approach to agricultural water standards that will provide flexibility to allow the standards to be applicable to diverse irrigation and growing conditions, while still protecting public health.

Question. For irrigation water testing, the growers in my state were hopeful that FDA or USDA could look into ways to identify local, federally-approved, resources that could test irrigation waters strategically for an entire system, instead of requiring individual owners to test the waters of every ditch and pipe. Are you considering ideas such as this?

Answer. As outlined in our Supplemental Notice, we proposed to allow data sharing among farms if the farms are taking samples from the same water source and no there is no reasonably identifiable source of likely microbiological contamination between sampling sites and the points at which the farms draw their water. In fact, we encourage such sharing when appropriate. We included a proposed provision (§ 112.45(e)) that would explicitly allow data sharing under certain circumstances.

Under proposed provision § 112.45(e), we are proposing that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent the farm's agricultural water source(s) and all other applicable requirements of part 112 are met. This provision would provide flexibility for a farm to determine the appropriate means by which to meet the proposed testing requirements in proposed § 1A112.45.

Under the supplemental proposed rule, farms using data collected by a third party or parties would still need to satisfy all applicable requirements of the proposed rule related to agricultural water testing. For example, the proposed rule includes requirements related to the timing of collection of samples, the number of samples collected, and specified analytical method to be used for testing, and recordkeeping.

We are currently evaluating the comments received on the topic and are carefully considering them in our efforts to determine an approach to agricultural water standards that will provide flexibility to allow the standards to be applicable to diverse irrigation and growing conditions, while still protecting public health.

QUESTIONS SUBMITTED BY SENATOR PATRICK LEAHY

First, I want to thank the Department and Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor for continuing to engage with the state of Vermont and our farmers and specialty producers. I hope that the Deputy Commissioner's many visits to the state have helped you to develop the best program possible for the industry, farmers, and consumers.

But states and farmers are nervous, and rightfully so. There are serious price tags attached to these food safety rules, not only for the Federal Government, but also for the states, and for our farmers of all sizes who do not have the infrastructure in place to meet these new rules. I think we need to acknowledge that we cannot implement these rules without adequate funding. The FDA cannot implement FSMA on its own without involvement from the states, and we cannot ask our states to take on this burden on their own. Finally, we cannot expect farmers to make such monumental changes on their farms without technical and financial support.

STATE BUDGET CONCERNS

Question. Vermont is one of 25 states that do not have any authority or capacity, or framework for that matter, to regulate the produce industry. With no guarantee that there will be Federal funds to support them in this work, I hope you can understand the reluctance these states have to develop a new produce program ahead of that promise of support and any funding.

What assurances can you give to this Committee and states like Vermont that the FDA will prioritize this food safety work in your fiscal year 2017 budget request?

Answer. The continued implementation of FSMA remains a key priority for FDA and fiscal year 2017 will be an important year for FSMA implementation. In particular, FDA plans are currently focused on areas such as implementation of the Produce Safety rule and continuing to enhance our import safety systems.

FDA is currently working with the Administration to determine the appropriation level of food safety funding to include in the fiscal year 2017 President's Budget. We are looking forward to discussing our future budget needs in more detail when that determination is complete.

Question. What will you be able to do if we continue to face lean Federal budget years and we are not able to fully fund this work through the appropriations process?

Answer. In FDA's own estimate of funding need, enactment of the President's budget authority request for food safety of \$1.3 billion, an increase of \$109.5 million above fiscal year 2015 would make it possible for FDA to move forward in fiscal year 2016 toward successful implementation of FSMA. At this time, FDA would focus its efforts on the Preventive Controls rules which were finalized in September. We must continue our education and outreach efforts to ensure that industry is prepared to comply with these finalized rules. Beyond fiscal year 2016, without the additional funding requested in the President's Budget, FDA would need to reexamine FSMA implementation efforts.

The success of building a modernized food safety system depends on FDA and industry working together, as well as working with State and other regulatory and public health partners, after the final FSMA rules are issued. Full funding of the President's budget authority request is essential to maintaining momentum toward timely and comprehensive implementation of FSMA and avoiding the disruption and

loss of effectiveness that would result if FDA, the states and the industry are not adequately prepared to get implementation right. Without adequate funding to support this strategy, FDA will be unable to perform its job under FSMA, and the American people will not see the full public health benefits of the law.

FDA is firmly committed to implementing FSMA the right way from the start. This means investing in the food safety culture change that is happening within FDA, but it also means being faithful to the comprehensive, holistic vision of food safety modernization laid out in FSMA. Congress directed FDA to build a modern food safety system, addressing food safety challenges across the spectrum of farms, manufacturers, and transporters of food, both domestic and foreign. The pieces of this system are closely interconnected and FDA cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers. Nor can FDA do the reverse, holding importers and foreign suppliers, but not domestic producers, to new requirements. FDA believes that if we do not implement the new FSMA-mandated food safety system in the comprehensive way Congress envisioned, from the start, we will fail to achieve the FSMA goals of food safety, strengthened consumer confidence, and a level playing field for U.S. producers.

Question. Are there ways to ease into the regulatory work the states will need to do until the FDA can provide them with the necessary amount of support?

Answer. The states will play a key role in gaining and maintaining compliance with the produce safety rule in the farming community, if funding permits. FDA is committed to working with our state partners to make this a reality. FDA is aware that there may be a variety of ways that states plan to assist and engage in facilitating and overseeing industry compliance with the produce regulation. These activities span from outreach and education to inspections on behalf of FDA or enforcement of comparable state requirements. FDA is also aware that the timeframe for states to engage in produce safety regulatory activities may vary widely. FDA is working with state representatives to develop implementation plans that provide for different collaboration models consistent with individual state's level of engagement in the produce safety regulatory paradigm. FDA is also exploring different mechanisms to oversee industry compliance in the event the state chooses to focus its activities solely on outreach and education or when additional time is needed by the state to establish an inspection program or to establish and enforce comparable state requirements.

SUPPORT FOR FARMERS

Question. In Vermont, where we are historically a dairy state, there are a lot of new diversified produce farms that are working on older dairy farms. That means they may not have metal processing equipment, or equipment they can sanitize, and there are exposed beams. Production agriculture most often takes place side-by-side with value added processing. For these farms, some of your rules will be a real challenge to meet as they look to modernize their operations. In a small state like Vermont, these requirements may cost upwards of hundreds of millions of dollars, funds these farmers simply don't have. I am struck that we do not have a "NRCS-like" agency at USDA or FDA to help the farmers to address food safety issues that are highlighted by these new rules. Running these farms out of business because of these costs cannot be the answer.

What partnerships can you develop with the U.S. Department of Agriculture (USDA) to help farmers make these infrastructure improvements?

Answer. FDA has been working with USDA for several years on all aspects of our produce safety regulatory program. For those small farmers that may need to add new food safety practices to their operations, FDA, in collaboration with USDA and other stakeholders, plans to offer guidance and other support to help them achieve compliance. More specifically, USDA staff worked with FDA to develop and review provisions of the produce safety regulation, and USDA staff are working with FDA and our state partners to develop post final rule implementation strategies and best practices that will enable state organizations to use their resources effectively. As mentioned above, FDA and USDA-NIFA are also co-funding one national and four regional coordinating centers for food safety training, which will focus on providing needed education and technical assistance to small and medium-sized farmers. FDA and USDA also jointly fund the Produce Safety Alliance, which is tasked with creating standardized curriculum covering FSMA requirements and good agricultural practices. The curriculum will include materials on understanding and performing a risk assessment for individual farms to consider in determining if infrastructure improvements may be needed. In addition, USDA administers a variety of grant,

loan and other financial assistance programs for which farmers may be eligible to apply.

Question. What new programs or authorities are needed to help our farms to modernize to comply with these new rules?

Answer. FDA is working at many levels to support programs aimed at assisting very small and small farmers to understand and comply with the produce safety rule. More specifically, FDA and USDA are funding educational opportunities to provide food safety training to produce farmers, such as training developed through the Produce Safety Alliance, so that they understand the basis of the requirements of the produce safety regulation and how to comply with the requirements. In addition, FDA has established a Technical Assistance Network to serve as a resource to respond consistently to questions from farmers and other stakeholders about interpretation and implementation of the produce safety regulation.¹ FDA is also working closely with our state partners to develop education and outreach programs that will provide important educational resources and tools to help farmers comply with the requirements.

Question. What should we tell a farmer in Vermont who cannot afford to make these improvements without Federal support?

Answer. It is FDA's intention to target our education efforts to the smaller businesses that may not be as familiar with our requirements, as well as some of the larger farms, so that they understand the regulations and have training and tools to comply with them.

Based on our outreach efforts and public comments, we proposed in September 2014 revisions to several key requirements of the original proposed rule on produce safety to be more flexible and less burdensome in key areas. For instance, we proposed a tiered and more targeted approach to water testing and revisions to the microbial standard for agricultural water used during growing produce (other than sprouts) that will be more flexible and less burdensome on farmers while still protective of public health. We removed the nine-month proposed minimum-time interval between the application of untreated biological soil amendments and harvesting until the agency collects and reviews further scientific evidence. We modified the definition of "farm" to help reduce the burden on a farm that packs or holds produce grown on another farm such that it would be subject to the produce safety rule and not also the preventive controls rule. The proposed rule also reduces the burden on small entities in part through the use of certain exemptions and limitations, and provides all farms flexibility for alternative practices to be used for certain requirements with adequate scientific support. In addition, States (including the state of Vermont, for example) could also submit a request for a variance for one or more requirements of the proposed rule. Finally, we proposed to provide farms that meet the definition of small and very small businesses an additional two and 3 years to comply with most provisions of the rule.

We recognize that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance with the new requirements. FDA is committed to working with the produce community and with partners in the USDA, state and local agencies, and foreign governments to facilitate compliance through education, technical assistance and guidance.

At the Federal level, USDA has opportunities designed to assist farmers with developing and growing their businesses. These opportunities come in several forms—including education; outreach; and grant, loan and other financial assistance programs—all of which are designed to provide farmers with resources to meet their individual needs. Further, FDA established the Technical Assistance Network that we intend to link to external Technical Assistance Networks; these networks will collectively serve as a resource for anyone subject to the regulations who needs assistance with rule interpretation and specific technical or scientific questions. We are counting on USDA's Cooperative Extension personnel, among others, to play a key role in the external Technical Assistance Networks to help provide assistance to the industry.

(Additional information to USDA's various grant programs is available at: <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=AMSGrants&leftNav=AMSGrants&page=AMSGrants&acct=AMSPW;http://www.grants.gov/search-grants.html?agencies%3DUSDA%7CDepartment%20of%20Agriculture>).

Again, FDA's ability to achieve our goal of successfully supporting farmers in compliance efforts is dependent on adequate funding.

¹For more information, see <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

The FDA is working with the USDA to establish one national and four regional food safety training centers. I am concerned that limiting delivery of food safety training nationwide to just these 5 centers may not effectively reach the grass-roots level and the targeted, intended beneficiaries.

Question. Will the FDA also provide funding for on-the-ground food safety training to be delivered by university extension programs, non-governmental organizations, and associations representing farms and small food processors/wholesalers?

Answer. The Agency recently released a FSMA training strategy², which outlines training options and delivery formats as well as introduces the partners in government, industry, and academia who are working with FDA on the development and delivery of training to the global community of food suppliers.

Industry training will be an important component of successful implementation of FSMA. The needs of small- and mid-sized farms and facilities are at the center of FSMA training development and will be met through multiple efforts:

- FDA has funded the creation of public-private Alliances (e.g., the Produce Safety Alliance, Food Safety Preventive Controls Alliance, and Sprout Safety Alliance) as a resource for industry and to facilitate widespread understand of the new requirements to support compliance.
- FDA is partnering with USDA's National Institute of Food and Agriculture (NIFA) to provide grants for food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers. Community-based organizations (CBOs), non-governmental organizations. Cooperative extension programs are among the eligible entities to receive grant funding, and the requests for applications have specified that this program will provide significant opportunities for funding through subcontracts and for partnerships with eligible stakeholder groups who work directly with the target audiences
- Recognizing the great diversity among members of the food industry, FDA will be funding cooperative agreements that will develop training options for local food production systems and tribal operations.
- The agency is partnering with the National Association of State Departments of Agriculture (NASDA) to collaboratively plan implementation of the produce safety rule. NASDA will help facilitate industry training while also having a role in the delivery of training to state regulators.

It will take time and adequate resources to make these efforts work. FDA is committed to making sure that everyone in the food supply chain knows what training and education resources are available, and how to gain access to them.

RISK ASSESSMENTS FOR SOFT-RIPENING AND RAW MILK CHEESE

Question. I have heard from many Vermont cheese producers who are concerned about regulations the FDA may develop that will impact the production of soft-ripening or raw milk cheese. These concerns were highlighted in comments submitted to the FDA by Allison Hopper, CEO of Vermont Butter & Cheese Creamery, who is a producer of soft-ripened cheese, and a member and past president of the American Cheese Society, and Catherine Donnelly, PhD, a University of Vermont professor and expert on the microbiological safety of food who has developed an extensive knowledge concerning sources of and mitigation strategies for control of *Listeria* in cheese making facilities. I will also include these comments in this hearing record.

I hope these comments will help inform the Quantitative Risk Assessment the FDA is developing. Specifically, I would like to highlight a point that I hope the FDA will take to heart. Your risk assessments on soft-aged cheeses and raw milk cheeses include data relating to illegal, unlicensed producers. These producers are operating outside of the law, and will likely do so regardless of any regulatory changes. However, as Deputy Commissioner Taylor has seen first-hand, our small artisanal cheese makers in Vermont undertake extensive quality and safety programs to ensure their cheeses are safe. I fear that any regulatory change could have severe impacts on these Vermont cheese makers, even though they currently meet or exceed current regulations. These risk assessments are no doubt limited by a lack of information, but they could also be prejudiced by these cases of illegal or unlicensed producers.

What assurances can you give me, and to Vermont cheesemakers, that you will work to remove any data pertaining to these illegal or un-licensed producers from the final risk assessment so they do not create an unfounded bias against the careful work and processes done by our legal cheese producers?

²<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm>

Answer. FDA recognizes the broad diversity in cheese manufacturing operations and approaches and has been working with the American Cheese Society in particular to learn more about artisanal cheeses and measures that cheesemakers take to ensure their products are safe. In conjunction with the July 2015 release of the joint FDA/Health Canada risk assessment on *Listeria monocytogenes* in soft-ripened cheeses, we announced a request for comments that would assist our efforts to identify and evaluate measures that might minimize the impact of harmful bacteria in cheeses made from unpasteurized milk. The Agency is committed to working and sharing an open dialogue with the artisanal cheesemaking community as we work on these efforts.

The joint FDA/Health Canada risk assessment published in July 2015 was first released as a draft risk assessment in 2012, and public comments were solicited. The public comments were considered and incorporated in the final assessment, as appropriate. In conducting the risk assessment, FDA followed best practices established by national and international institutions, which include taking steps to reduce any possible bias that could be introduced by the data used, conducting a peer-review process, and providing an opportunity for public comment.

Question. I and others have worked hard to support and cultivate the artisanal cheese industry here in the United States. How are you working to harmonize our cheese regulations with the European Union so that we do not create trade barriers or risk American jobs?

Answer. FDA is not currently undertaking efforts to harmonize its cheese regulations with those of the European Union. As far as FDA knows, not harmonizing our cheese regulations with those of the European Union is not having a detrimental impact. That being said, FDA welcomes feedback on this issue and is committed to working and sharing an open dialogue with the artisanal cheesemaking community. The Agency remains dedicated to ensuring a safe and wholesome food supply using the latest science to protect human health, and promoting dialogue with industry, consumers and other interested parties.

SUBCOMMITTEE RECESS

Senator MORAN. Again, thank you for your testimony. Thank you for the way that you have answered questions today and have presented testimony. And please express my gratitude to the folks at FDA for the outreach that has occurred in the development of these orders of control.

With that, the subcommittee stands adjourned.

[Whereupon, at 3:26 p.m., Wednesday, September 16, the subcommittee was recessed, to reconvene subject to the call of the Chair.]