DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT

OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

UNITED STATES SENATE

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I. 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 thatendanger the public health.

II. 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 (FY) 2016 budget request is so essential to the success of FSMA.

III. 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).

IV. 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.

V. 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.

VI. 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.

<u>Preventive Controls in Food Facilities: Blue Bell Creamery</u>

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.

VII. FDA's FY 2016 President's Budget Request for Food Safety

The FY 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 FY 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 FY 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 FY 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 FY 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 FY 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 FY 2016 FSMA funding request.

VIII. 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.