



TESTIMONY OF

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

IMPLEMENTING THE FDA FOOD SAFETY MODERNIZATION

ACT

BEFORE THE

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INTRODUCTION

Good morning, Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. I am Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the Agency's ongoing implementation of the FDA Food Safety Modernization Act (FSMA), which was signed into law in January 2011. I commend you and the Members of the full committee for your leadership in achieving enactment of this landmark legislation.

Food safety is a core public health issue. Every year, one in six Americans suffers from a foodborne illness. Preventing foodborne illnesses will improve public health, reduce medical costs, and avoid the costly disruptions of the food system caused by illness outbreaks and large-scale recalls. In our increasingly interconnected world, we need a strategy that meets the public health demands of a global marketplace and addresses the complexities and challenges of food safety in the 21st century.

Let me take a moment to recall the environment in which this Committee considered FSMA's passage, involving a cascade of food-related health crises. Domestically, for example, there was the 2006 *Escherichia coli* (*E. coli*) spinach outbreak that sickened more than 200 people and killed three; the 2006-2007 *Salmonella* contamination from Peter Pan and Great Value peanut butter that caused over 600 serious illnesses, including more than 100 hospitalizations; and the 2009 *Salmonella* outbreak, which resulted in more than 700 illnesses, more than 150 hospitalizations, and nine deaths, linked to the Peanut Corporation of America, in which a small Georgia firm's peanut product was sold to dozens of larger firms and ended up contaminating

hundreds of different products and potentially endangering millions of our citizens.

Internationally, in 2007, the addition of the industrial chemical melamine to pet food ingredients in China, that were then used to make pet food in the United States, sickened and killed thousands of cats and dogs in the United States.

These were on top of dozens of smaller outbreaks that received less publicity but contributed to the annual toll of 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths that the Centers for Disease Control and Prevention estimates occur each year from contaminated food. While we will never have a zero-risk food supply, most of these illnesses, hospitalizations, and deaths could be prevented through the full implementation of the modernized food safety system created by FSMA.

Beyond the obvious human and animal suffering, and the associated economic costs to sickened consumers, there are tremendous economic costs to food producers. The 2006 *E. coli* outbreak linked to spinach, for example, resulted in the destruction of much of that year's spinach crop and reduced retail spinach expenditures by an estimated \$200 million.¹ The economic impact of the 2009 Peanut Corporation of America product recalls was estimated by some to be up to \$1 billion.² In fact, it is estimated that the overall negative economic impact of foodborne illness in the United States, including medical costs, quality-of-life losses, lost productivity, and lost-life expectancy, may be as high as \$77 billion per year.³

¹ <http://www.ers.usda.gov/amber-waves/2010-march/consumers%E2%80%99-response-to-the-2006-foodborne-illness-outbreak-linked-to-spinach.aspx>

² <http://www.gpo.gov/fdsys/pkg/CHRG-111hhr47797/html/CHRG-111hhr47797.htm>

³ Scharff, R.L, 2012. Economic Burden from Health Losses Due to Foodborne Illness in the United States. *Journal of Food Protection* 75(1): 123-131.

With those stark problems in mind, the Congress and the President enacted the most sweeping reform of our Nation's food safety laws in more than 70 years, giving FDA the tools necessary to help eliminate such threats to our food. As you know, FSMA aims to enhance the safety of the U.S. food supply by shifting the focus from responding to contamination to preventing it. The law gives FDA important new tools to hold domestic and imported foods to the same food safety standards and directs FDA to build an integrated national food safety system in partnership with Federal, state, local, territorial, and tribal authorities. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The modernization of FDA's regulatory framework for the oversight of food is one of the most challenging initiatives in FDA's history, but one that will have public health and economic benefits that could save thousands of lives and billions of dollars annually.

In my testimony today, I will discuss the seven key proposed rules FDA has published to implement the preventive approach required by FSMA. I will also discuss a few of the significant new enforcement tools FSMA provides to enhance our ability to protect consumers. Lastly, I will mention the importance of having sufficient resources to achieve the food safety enhancements envisioned by FSMA.

PREVENTIVE STANDARDS

I would now like to highlight the Agency's activities related to the seven foundational rules which form FSMA's central framework aimed at systematically building preventive measures across the food system, from the farm to the table. This framework is comprised of measures to keep produce safe, implement modern preventive controls in human and animal food facilities,

modernize oversight of imported foods, guard against intentional contamination, and help ensure the safe transport of food and feed.

Preventive Controls for Human Food and Produce Safety Standards

In January 2013, FDA issued two proposed rules to lay the foundation for focusing more on preventing food safety problems rather than reacting to problems after they occur: the proposed preventive controls for human food rule,⁴ which would implement provisions of section 103 of FSMA, and the proposed produce safety rule,⁵ which would implement section 105 of FSMA.

The proposed rule on preventive controls for human food would require food facilities to have a written plan in place to identify potential hazards, put in place steps to address them, verify that the steps are working, and outline how to correct any problems that arise. The proposed rule on produce safety, which would apply to both domestically produced and imported produce, would require farms that grow, harvest, pack, or hold fruits and vegetables covered by the proposed rule to follow certain standards aimed at preventing microbiological contamination of their produce.

The proposed rules we put forth were the result of extensive outreach by FDA with consumers, government, industry, researchers, and many others. Since their release, we have made every effort to solicit input on the proposed rules, not only through the standard rulemaking process, but also by participating in nearly 200 webinars, listening sessions, and other activities with various industry, consumer, and other stakeholder groups across the country and internationally. To ensure broad input and facilitate constructive dialogue, FDA extended the comment periods on the proposed rules three times. The comment periods ended on November 22, 2013. During

⁴ “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-01-16/pdf/2013-00125.pdf>.

⁵ “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-01-16/pdf/2013-00123.pdf>.

the comment period, FDA received, and is now considering, over 7,000 comments on the proposed preventive controls for human food rule and over 15,000 comments on the proposed produce safety rule.

In December 2013, we announced that, based on our discussions with farmers, the research community, and others, we have learned a great deal, and our thinking has evolved. We recognize that the new safety standards must be flexible enough to accommodate reasonably the great diversity of the produce sector, they must be practical to implement, and they must be based on the best available science. To achieve this goal, we believe that significant changes will be needed to key provisions of the two proposed rules affecting small and large farmers. These provisions include water standards and testing for domestically produced and imported produce, standards for using raw manure and compost relating to preventing microbiological contamination of produce, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms. We intend to publish revised proposed rule language on certain provisions by early summer 2014 and accept comments on those provisions. We value our ongoing dialogue with produce farmers and others in the sector on the proposed rules and want to ensure that we implement FSMA in a way that improves public health protections while minimizing undue burden on farmers and food processors.

FDA also recognizes that FSMA will only be as effective as its on-the-ground implementation. Building a national integrated food safety system has long been a foundational element of our Nation's strategy for carrying out an effective and efficient food safety program. It is also one of the key themes of FSMA, which calls for enhanced partnerships and integration with our Federal, state, local, and other partners. 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 new requirements under FSMA. FDA is committed to working with the produce community and with partners in the U.S. Department of Agriculture (USDA), state departments of agriculture, state and local health agencies, tribal and territorial authorities, and foreign governments to facilitate compliance through education, technical assistance, and regulatory guidance.

For those farms that may need to add new food safety practices to their operations, FDA, in collaboration with USDA and other stakeholders, will offer technical assistance and work with small farmers. FDA established the Produce Safety Alliance, a partnership with USDA and Cornell University, to provide educational materials to the agricultural community. The Alliance is aimed at giving produce growers and packers training, educational materials, and other opportunities to learn about current risk- and science-based best food safety practices and the future regulatory requirements.

Similarly, for the proposed preventive controls for human food rule, FDA, in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, has established the Food Safety Preventive Controls Alliance, which will develop training courses and materials on preventing contamination for both human and animal food. The materials to be developed by the Alliance will help industry—particularly small- and medium-sized companies—comply with the new preventive controls rule.

Preventive Controls for Food for Animals

In October 2013, FDA released its preventive controls for food for animals proposed rule,⁶ which, along with the preventive controls for human food rule, would implement provisions of section 103 of FSMA. This proposed rule would improve the safety of animal food, including pet food and food for food-producing animals, by requiring animal food facilities to take preventive steps to ensure that food for animals is safe. The proposed rule would establish requirements for current good manufacturing practices for the manufacturing, processing, packing, or holding of animal food and require certain facilities to also implement hazard analysis and risk-based preventive controls for food for animals. These measures will help prevent foodborne illness in animals as well as help prevent transmission of pathogens such as *Salmonella* to individuals handling the food, such as pet food. FDA held three public meetings specifically on this proposed rule and extended the comment period until March 31, 2014, in response to requests to allow additional time for interested parties to comment.

Enhancing the Safety of Imported Food

FDA's success in protecting the American public depends increasingly on its ability to reach beyond U.S. borders and engage with its government regulatory counterparts in other nations, as well as with industry and regional and international organizations, to encourage the implementation of science-based standards to ensure the safety of products before they reach our country.

Today, about 15 percent of all food consumed in the United States is imported, and this number is even higher in certain categories. Nearly 50 percent of fruits, 20 percent of vegetables, and

⁶ "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/pdf/2013-25126.pdf>.

80 percent of all seafood consumed in the United States are imported. The rapid globalization of the food supply poses many challenges. First and foremost, there is the matter of volume. Whereas imports of food into the United States amounted to only a few hundred thousand shipments annually in the early 1990s, this year we expect to see over 12 million food shipments arrive at U.S. ports. Second, the nature of imports has changed. The staple goods, such as sugar, spices, and molasses, that we imported a century ago have expanded to every conceivable commodity—fresh fruits and vegetables, canned and other processed and ready-to-eat foods, food preservatives, emulsifiers and stabilizers, seafood, apple juice, cheeses, and many more. Furthermore, commodities today are often comprised of ingredients from many different countries, making the inspection process more difficult and traceback more complicated.

FSMA includes significant changes to FDA’s food safety authorities, with the fundamental goal of asking importers and foreign food producers to take greater responsibility in protecting food before it is transported to this country. FSMA’s new import authorities will enhance FDA’s ability to help ensure the safety of imported food by building in new processes throughout the supply chain. In July 2013, FDA issued two proposed rules covering food imported into the United States to make importers more accountable for food safety and enhance FDA’s ability to use credible third parties to monitor conditions and standards in foreign facilities that produce and process food. These two proposed rules would provide important verification that imported food meets the same food safety standards as domestic product.

The foreign supplier verification proposed rule,⁷ which would implement section 301 of FSMA,

⁷ “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-29/pdf/2013-17993.pdf>.

would require importers to perform certain risk-based activities to verify that food imported into the United States has been produced using processes and procedures that provide the same level of public health protection as those required of domestic food producers under the preventive controls or produce safety regulations. The accredited third-party auditor certification proposed rule,⁸ which implements section 307 of FSMA, would establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. Having comprehensive oversight of a credible and reliable program for third-party audits and certifications of foreign food facilities and food would help in making admissibility decisions when FDA has determined that an imported food may pose a food safety risk and in facilitating rapid entry of food under a new voluntary program FDA is developing for that purpose.

The Agency held two public meetings on the import proposed rules and, similarly to the other FSMA proposed rules, conducted webinars, listening sessions, and further outreach to both domestic and international stakeholders to explain the proposals and provide additional opportunity for stakeholder input. The public comment period for the proposed rules closed on January 27, 2014, and FDA is now reviewing all comments received.

Protecting Food Against Intentional Adulteration

Section 106 of FSMA directs FDA, in coordination with the Department of Homeland Security and in consultation with USDA, to issue new regulations to protect against the intentional adulteration of food. In December 2013, FDA released for public comment its intentional

⁸ “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications” proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-29/pdf/2013-17994.pdf>.

adulteration proposed rule,⁹ requiring that larger food businesses in the United States and abroad take steps to prevent contamination of the food supply in cases where the intent is to cause wide-scale public harm. Under the proposed rule, food facilities would be required to complete and maintain a written food defense plan that assesses their vulnerabilities to intentional adulteration where the intent is to cause public health harm, including acts of terrorism, and identify and implement strategies to minimize or prevent these vulnerabilities.

This is the first time the Agency has proposed a regulatory approach for intentional adulteration of the food supply. Although intentional acts to contaminate the food supply in order to cause large-scale public harm are unlikely to occur, the potential loss of life and harm to the economy could be significant and, whenever possible, must be prevented. Our goal is to devise a regulation that makes a practical difference for food safety while being cost effective, which we know is a significant challenge in the case of intentional adulteration. We look forward to engaging with stakeholders and receiving public input to help us refine our approach and further focus the scope of the rule. Comments are due on the proposed rule by March 31, 2014, and we have three public meetings scheduled for February and March to explain the proposal and provide additional opportunity for input.

Ensuring the Sanitary Transport of Food

Last week, FDA put forth a proposal for the seventh, and final, major rule to implement the overarching public health and safety goals of FSMA. The sanitary transport of food proposed

⁹ “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” proposed rule available at <http://www.gpo.gov/fdsys/pkg/FR-2013-12-24/pdf/2013-30373.pdf>.

rule¹⁰ would establish transportation practices for shippers, receivers, and carriers by motor or rail vehicle engaged in transporting both human and animal food. The proposed rule would implement section 111 of FSMA as well as the Sanitary Food Transportation Act of 2005.

Before the enactment of FSMA, FDA had commissioned a study to obtain more information on the subject, had published an advance notice of proposed rulemaking, and started to evaluate the resulting data to move forward with the rulemaking.

The proposed rule would establish requirements to help ensure that human and animal food are not adulterated because they have been transported or offered for transport under conditions that are not in compliance with the sanitary food transportation regulations. The goal is to stop practices that create food safety risks, such as the failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food during transportation.

FDA is soliciting comments on the proposed rule and will conduct a public meeting on the issue.

NEW INSPECTION AND ENFORCEMENT TOOLS

FSMA recognizes that FDA must have the clear mission and tools to verify compliance with the new prevention standards and respond effectively to protect consumers when problems emerge despite preventive controls. We welcome these new mandates and authorities and believe they are critically important to our mission of ensuring the safety and security of our Nation's food supply. For example, FSMA gave FDA its first inspection frequency mandate for food facilities, as well as enhanced access to the records documenting a firm's implementation of its food safety

¹⁰ "Sanitary Transportation of Human and Animal Food" proposed rule available at <https://www.federalregister.gov/articles/2014/02/05/2014-02188/sanitary-transportation-of-human-and-animal-food>.

plan. In addition, before the passage of FSMA, FDA was able to detain a food product only when it had credible evidence that a food product presented a threat of serious adverse health consequences or death to humans or animals. FSMA amended the criteria, so that FDA can prevent unsafe food from reaching consumers by detaining food it has reason to believe is adulterated or misbranded.

FSMA also provides the Agency with the authority to issue a mandatory recall for foods (other than infant formula, for which FDA already has recall authority) when a company fails to voluntarily recall certain foods that may be unsafe after being asked to do so by FDA. In addition, the Agency can now deny entry to an imported food if a foreign facility refuses an FDA inspection. These new enforcement tools, combined with FDA's new authority under FSMA to suspend the registration of a facility if the Agency determines that the food poses a reasonable probability of serious adverse health consequences or death, enable FDA to more effectively prevent unsafe food from entering commerce.

RESOURCES

The determination that we have all made to improve the safety of our food supply requires two fundamental steps. The first was to give FDA the mandate and tools to modernize the food safety system, and I applaud you for doing that via the enactment of FSMA. The second is to give FDA the capacity to carry out the numerous changes embodied in the law. It is that challenge that we must continue to address. Simply put, we cannot achieve our objective of a safer food supply without a significant increase in resources.

At the time of passage of FSMA, the Congressional Budget Office estimated that FDA would

need an increase in its base funding for food safety of over \$580 million.¹¹ Last year, in a report to the Congress on food safety program and resource needs required by FSMA, the Secretary of HHS (based on different assumptions and a commitment to efficiency) reported a need for an increase over FDA's Fiscal Year (FY) 2012 food safety funding base in the range of \$400 to \$450 million.¹² We will continue our efforts to make the best use of the resources we have, but I can say with absolute certainty that we cannot do all that is asked of us without additional resources.

Let me give you an example, referring back to our discussion of food imports. Imported food shipments have increased from about 400,000 per year in the early 1990s to about 12 million today but, clearly, our resources have not kept up with this exponential growth. Moreover, FSMA demands that FDA do many more things in the import area, which really amount to creating a significantly enhanced system for helping to ensure the safety of imported food. A significant shift in the way we oversee importers comes from a new provision that places responsibility on U.S. importers to ensure the safety of the food they bring into this country. But FDA now has the new mandate to oversee these importers, as well as continue its border operations and foreign inspections. Without adequate funding, FDA will be unable to adequately fulfill its oversight responsibilities. This includes implementing the Foreign Supplier Verification Program, which requires new staff and skills to audit and verify the adequacy of the importer's verification plan; conducting more foreign inspections; working more closely on food safety with foreign governments to leverage their efforts; and improving our data and import systems to facilitate prompt entry of foods that meet our safety standards. The Congress was

¹¹ <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/117xx/doc11794/s510.pdf>

¹² <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf>

right in mandating this new system, which is needed to protect consumers. This need was demonstrated again in 2013 by significant outbreaks of foodborne illness involving the Hepatitis A virus linked to pomegranate seeds from Turkey, which resulted in 162 illnesses and 71 hospitalizations, and the *Cyclospora* parasite, which resulted in 631 illnesses and 49 hospitalizations, for which some illness clusters were linked to produce from Mexico. But we cannot meet this need without the resources it takes to build the new import system.

Another example of the need for additional resources is our direction from the Congress in FSMA to partner with state and local agencies and build their capacity to assist the Federal government in protecting the food supply. This is especially crucial for produce safety, where we were reminded again in 2011 by the tragic *Listeria monocytogenes* outbreak linked to whole cantaloupes from Jensen Farms, which killed 33 people and resulted in 147 illnesses, just how essential it is to properly implement FSMA's new produce safety provisions. States have built-in advantages in working with growers. While we are working with growers and other stakeholders to get the rules right, after that, we must be able to partner with state departments of agriculture, other state partners, and local, territorial, and tribal authorities to deliver the education, training and technical assistance, as well as compliance oversight, needed to ensure the rules are implemented properly. This cannot be done, however, unless we find additional resources to build the capacity of our partners and provide the needed assistance to growers, especially small and mid-size operators. State, local, and other partners are willing to step up, not only in the produce area but all areas of food and feed safety, and take on much of this responsibility. However, current appropriations simply do not give us the funding to take advantage of this opportunity and carry out the congressional directive.

We are, of course, grateful for the additional food safety funding the Agency has received to date through the appropriations process. Fully implementing the law, however, will require a substantial and reliable stream of funding. The President's FY 2014 Budget proposed two fees that would go a long way toward helping FDA meet its food safety obligations under FSMA while also providing benefit to the affected industry and our state, local, territorial, and tribal partners.

One of the proposed fees is a registration fee for those domestic and foreign food facilities which are required to register with FDA. With these resources, FDA will increase its capacity to establish an integrated national food safety system and further strengthen food safety inspection, research, and import review.

The second proposed fee is an import user fee of a minimal amount (approximately \$20) per line entry. A "line entry" means each portion of a shipment offered for import that is listed as a separate item on an entry document. These fees would help FDA implement the new import-related programs required by FSMA to enhance the safety of imported food and will provide benefits to foreign food producers, U.S. food importers, and the general public. For importers in particular, the user fee will result in an improved import program resulting in greater efficiency and predictability for their businesses. The improvements to the import process will not only facilitate the entry of safe products but also improve public health by enabling FDA to focus its attention on higher risk products. The ultimate result will be improved confidence in the safety of food from abroad.

FDA would like to work with you as well as our other stakeholders to develop these user fees.

CONCLUSION

The Agency has mobilized significant resources toward the development of proposed and final rules mandated in FSMA and continues to work as expeditiously on the rulemakings and other implementation activities as its resources allow. Though the regulation development process can be challenging and time consuming, the broad preventive controls framework envisioned in FSMA is critical to enhanced food safety for U.S. consumers and is an important priority for the Agency.

It is gratifying to FDA that in our meetings around the country, we have received broad support for moving forward in implementing FSMA in a timely manner in light of its important food safety goals. We will continue our collaborative approach as we move down the pathway to final rules and to full implementation of FSMA.

Thank you for the opportunity to discuss FDA's continuing efforts to implement FSMA. I again would like to commend you for your leadership in enacting this important legislation which, when fully implemented, will provide significant protections to consumers from foodborne illnesses. I would be happy to answer any questions.