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# EXAMINING THE IMPLEMENTATION OF THE FOOD SAFETY MODERNIZATION ACT

## HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

## COMMITTEE ON ENERGY AND COMMERCE

## HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

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# EXAMINING THE IMPLEMENTATION OF THE FOOD SAFETY MODERNIZATION ACT

**WEDNESDAY, FEBRUARY 5, 2014**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Shimkus, Murphy, Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Walden, Barton, Upton (ex officio), Pallone, Dingell, Capps, Matheson, Green, Butterfield, Barrow, Christensen, and Waxman (ex officio).

Staff present: Matt Bravo, Professional Staff Member; Noelle Clemente, Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Chris Sarley, Policy Coordinator, Environment and the Economy; John Stone, Counsel, Health; Ziky Ababiya, Democratic Staff Assistant; Eric Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; and Karen Nelson, Democratic Deputy Staff Director, Health.

Mr. PITTS. The Chair will recognize himself for an opening statement.

## OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

According to the Centers for Disease Control, 48 million Americans, or one in six, will become ill from a foodborne disease each year. One hundred and twenty-eight thousand people will require hospitalization, and 3,000 will lose their lives as a result. Sadly, many of these diseases and deaths could have been prevented if proper safety precautions had taken place on the farm, in processing facilities, and while transporting foods.

The Food Safety Modernization Act (FSMA), the most far-reaching reform of the Food and Drug Administration's food safety authority since the 1930s, was signed into law in January 2011. The law tasked FDA with issuing major regulations covering such topics as preventative controls for human food and animal feed, produce safety, foreign supplier verification, accreditation of third-

party auditors, intentional adulteration, and sanitary transportation, among others.

I am particularly interested in the sanitary transportation proposal released last Friday. Since mid-2011, I have been following stories about commercial food trucks without proper refrigeration carrying perishable foods along our Nation's highways at dangerously high temperatures, and a subsequent investigation by the Indiana State Police. Perhaps Deputy Commissioner Taylor can speak to how the proposed rule would address situations like this.

I would like to commend Mr. Taylor for his outreach efforts and dialogue with all parts of the food supply chain prior to the release of these proposed rules and also for extending comment periods on issues unique to certain sectors of the industry, such as farmers. This conversation must continue.

I believe the success of FSMA's implementation will rest on a flexible regulatory structure that, one, encourages an efficient, risk-based approach to food safety, and two, acknowledges that a one-size-fits-all, overly burdensome model simply will not fit such a vast and diverse food supply chain such as ours.

In issuing its proposed regulations, FDA has released compliance cost estimates that differ significantly with outside estimates, and I would be interested in learning about the assumptions and methodology the agency used to arrive at these figures.

Additionally, over the last few years, many parts of the food industry have voluntarily made progress toward preventing foodborne illness, and I would hope FDA would not punish these good actors as it seeks to bring the rest of the industry up to standard.

I would also ask Mr. Taylor for a commitment to work with industry, particularly with respect to inspections, after the final regulations go into effect. A collaborative, rather than adversarial, relationship with industry will yield greater compliance and ultimately further our goal of making the U.S. food supply the safest it can be.

Finally, while we need to finalize FSMA's regulations in a timely manner, I am concerned by the court-ordered deadline of June 30, 2015. These regulations are too important to be rushed through without proper thought and consideration.

I would like to welcome Mr. Taylor and thank him for appearing before us today. I look forward to his testimony.

[The prepared statement of Mr. Pitts follows:]

## PREPARED STATEMENT OF HON. JOSEPH R. PITTS

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I would like to welcome Mr. Taylor and thank him for appearing before us today, and I look forward to his testimony.

Mr. PITTS. At this time I will yield the remainder of my time to Ms. Blackburn.

**OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE**

Mrs. BLACKBURN. And we do welcome you and are pleased that you are here. Thank you so much for taking the time to be here and for giving us the opportunity to talk with you and look at the FSMA and a look at food safety and the FDA and the responsibilities that exist by regulations, the guidance documents that affect the wide array of individuals and industries that are associated with our Nation's food supply. Everyone wants a secure food supply, and they don't want it to be burdensome and cumbersome and difficult, and they want some certainty in the process.

Since January 2013, the agency has issued a number of proposed rules and received a significant amount and number of comments. We hope we have the opportunity to review some of this with you today and look forward to making certain that we are all moving in the right direction for food security.

I yield back.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the ranking member, Mr. Pallone, for 5 minutes.

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. PALLONE. Thank you, Chairman Pitts, and thank you, Mr. Taylor, for being here today.

I appreciate the opportunity to check in with the Food and Drug Administration on its implementation of the FDA Food Safety Modernization Act, or FSMA. With the passage of FSMA 3 years ago, Congress gave FDA new tools to shift the food safety system from one that reacts and responds to food safety incidents to one that prevents them.

FSMA provided the first major overhaul of Federal food safety laws since the 1930s, and it was enacted at a time when the public health challenges of an evolving domestic and global food supply chain were evident in a series of foodborne illness outbreaks and contamination incidents, and I am proud to have worked with my colleagues, Mr. Dingell and Mr. Waxman and Ms. DeGette, on food safety legislation that emphasizes a prevention and risk-based approach to food safety from farm to table, both for domestic and imported food, and ultimately to have supported the passage of FSMA. Food safety is and should be a bipartisan issue, and I hope we in this committee will continue to do what we can to support progress in the modernization of our food safety system.

We have seen in the last year the rollout of many significant parts of the law, including proposed rules for major framework elements such as produce safety standards, preventive controls, and oversight of food imports. I appreciate the work FDA has done in engaging with stakeholders and incorporating public input into the development of these proposed rules. However, I continue to urge FDA to enact final FSMA rules as expeditiously as possible because the safety of U.S. consumers' food supply should not be put at risk.

In addition, the passage of FSMA did not end our work on protecting the public health from foodborne threats. There are 48 million Americans every year who get sick from foodborne illnesses, as estimated by the Centers for Disease Control and Prevention, and there are still several thousand deaths each year attributed to foodborne disease.

In order to ensure that the safety benefits of FSMA will be fully realized, Congress must provide adequate resources to the FDA for implementation. The Congressional Budget Office estimated that the law could require $1.4 billion over 5 years to roll out, but the agency has received only a fraction of that in resource increases, not to mention the impacts of sequester.

The food import user fee and food facility registration and inspection user fee proposed in the President's budget could also substantially support the implementation of the modern, effective food safety system envisioned in FSMA. I support the idea of utilizing such food-related user fees, which I believe can benefit both industry and government by reducing foodborne illnesses and the associated costs, which can be significant. The estimated overall economic total of outbreaks is almost $80 billion annually.

With the health and safety of the American public at risk, we can't leave the job only half done by not adequately funding FDA to fully implement this important law.

And again, thank you, Mr. Chairman, and I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BURGESS. Well, thank you, Mr. Chairman, and I appreciate, Mr. Taylor, you being here with us this morning and your willingness to discuss the implementation of the Food Safety Modernization Act and the shifting focus of food safety from reaction to prevention.

I must say, I am concerned that some of the rhetoric and initial goals for the process have not been matched by the proposed rules that have been released. The Food and Drug Administration did have substantial interaction with stakeholders initially but it seems that the rulemaking process was only prompted to completion by actions in the courts. Therefore, I am concerned that stakeholder comments were not adequately addressed in the proposed rulemaking. We should encourage the Food and Drug Administration to implement the Food Safety Modernization Act through a scientific and risk-based approach that addresses the needs and concerns of the companies that the laws affect.

Many companies and industries in the food supply system have been proactive and have implemented innovative methodologies to address the changing landscape of the food supply system. Companies should continue to identify microbiological and chemical hazards and implement preventive controls to effectively mitigate risk. We should promote an environment that encourages innovation and moves away from a one-size-fits-all regulation. And let me just say, as we sit here now over 3 years since the Food Safety Modernization Act was signed into law, I think it is significant that we are having this meeting, this hearing in February of this year.

Look, we all know what is going to happen when the weather heats up. We are going to have an outbreak. I don't know of what. I don't know where it will occur. But you have seen it, I have seen it through several years on this committee. We will be talking about salmonella, we will be talking about E. coli. I would like to know what is going to be different this year than has happened in previous years. What are you doing proactively with the new tools you have in the Food Safety Modernization Act that are going to allow us to perhaps predict and prevent but at least mitigate the damage from these outbreaks that we all know will occur. And Mr. Pallone talked about the fact that the Food Safety Modernization Act was necessary, the first time it had been undertaken in decades. It was necessary because of the evolving nature of the global risk that was presented to our food supply, and as a consequence we both know that that evolving of the global risk has not changed. It has not diminished since the signing into law of the Food Safety Modernization Act. So if anything, it is even more critical this February than it was five Februarys ago or 10 Februarys ago. Our food supply system varies greatly across the United States. Certainly, a one-size-fits-all approach cannot address the needs of U.S. food suppliers effectively. I hope we can continue to work with your

agency and the stakeholders to ensure that the food supply system has the flexibility needed to allow the industry to tailor their programs to their unique product needs while also ensuring the highest food safety benefits for all consumers.

Thank you, Mr. Chairman, for the recognition. I will yield back to you.

Mr. PITTS. The Chair thanks the gentleman and now recognize the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. WAXMAN. Thank you very much, Mr. Chairman.

In December 2010, Congress passed the most significant overhaul of FDA's oversight of food safety since passage of the Food, Drug, and Cosmetic Act in 1938. The FDA Food Safety Modernization Act, FSMA, we call it, represents a fundamental shift in how FDA approaches food safety, focusing on prevention instead of reaction.

It requires food facilities to develop procedures to prevent food contamination and to take corrective actions when contamination is discovered. It requires FDA to establish standards for the safe production and harvesting of fruits and vegetables. It mandates increased FDA inspections for both domestic and foreign facilities and gives FDA access to records relating to food safety. It gives FDA mandatory recall authority and improves its ability to detain unsafe food, and it gives FDA better tools to oversee the safety of imports. It encourages FDA to work with other Federal, State, local, and foreign agencies to more efficiently achieve food safety goals.

It is an ambitious law, even just on an administrative level. It requires FDA to prepare more than 50 regulations, guidances, reports, and studies in a short timeframe. Already, FDA has published proposed versions of the seven most important regulations. Given their complexity, their need to fit together and complement each other, and the breadth of their reach, these regulations were not easy to develop. Their release is an accomplishment for which FDA should be proud.

But now, of course, FDA must finalize them. I recognize the political pressure put on the agency to delay and re-propose. I also recognize the importance of ensuring that the regulations are workable and that they appropriately address the wide range of activities that they cover. But American consumers need FDA to act without further delay.

We all have heard the statistics. According to the Centers for Disease Control, every year 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. The goal of the law is to substantially lower those numbers. American consumers will not get its full benefits until the rules are all finalized, and that is why FDA needs to finalize them as quickly as the agency can.

Mr. Chairman, I thank you for holding this hearing. It will be good to get an update from FDA on how the implementation of this

extensive legislation is going. I hope FDA will also share with us the impact the current lack of user fees is having, or is likely to have, on its ability to fully implement the law and protect public health. I would prefer that we fully fund FDA through appropriations. However in today's political environment, that is not going to happen.

Enhancing food safety is in everyone's interest, Republicans and Democrats, consumers, farmers, and manufacturers. We should be doing everything we can to give FDA the resources it needs to make full use of its new authorities under the Food Safety Modernization Act.

Mr. Chairman, I look forward to the testimony. I want to apologize in advance. There is another subcommittee meeting simultaneously with this one, and I may not be here for the full opportunity to hear the testimony. I will try to get back for questions.

I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman.

On our panel today, we have Mr. Michael Taylor, Deputy Commissioner, Food and Veterinary Medicine, U.S. Food and Drug Administration. Thank you for coming. Your written testimony will be made part of the record. You will have 5 minutes to summarize.

At this time, the Chair recognizes Mr. Taylor for 5 minutes for an opening statement.

**STATEMENT OF MICHAEL R. TAYLOR, DEPUTY COMMISSIONER FOR FOODS AND VETERINARY MEDICINE, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH & HUMAN SERVICES**

Mr. TAYLOR. Thank you very much, Mr. Chairman, and good morning, Chairman Pitts, Ranking Member Pallone and members of the subcommittee, and first thank you for convening this hearing and giving us an opportunity to discuss the implementation of the Food Safety Modernization Act.

As you know, food safety is a fundamental public health concern and it is a topic on which the public does have high expectations, and unfortunately, as many of you have noted already, too many Americans get sick every year, too many go to the hospital and too many die due to foodborne illness, and the costs are high, estimated as high as $77 billion just in the costs associated directly with foodborne illness.

We will never have a zero-risk food supply, Mr. Chairman, but as the statements have indicated, most foodborne illnesses are in fact preventable. By preventing foodborne illness, we can improve public health, reduce medical costs and avoid costly disruptions of the food system, and with food imports having risen many-fold over the last 2 decades, we need a strategy that also addresses the complexities and challenges of food safety in today's global food system.

Fortunately, Mr. Chairman, FSMA provides us with that strategy. It is a risk-based prevention strategy that builds on what the food industry and food safety experts have learned works to prevent harmful contamination and reduce foodborne illness. FSMA recognizes the primary responsibility and capability of those who produce food to make it safe. It calls on FDA to issue regulations aimed at ensuring practical steps are taken throughout the farm-

to-table system, as you have indicated, addressing produce safety, processing facilities, transport, and so forth.

FSMA also provides FDA new inspection mandates and enforcement tools that we can use to help ensure high rates of compliance with FSMA's new standards, which is how we will achieve the food safety and economic benefits that motivated FSMA's enactment, getting high rates of compliance with the rules once they are issued.

One of FSMA's most important themes and one that we at FDA take very much to heart is partnership. FSMA directs us to work with CDC to improve foodborne illness surveillance, with the Departments of Agriculture and Homeland Security to help get our standards right, and, very importantly, with our State, local, territorial, tribal and foreign government partners to support and oversee implementation of FSMA standards. In fact, the centerpiece of FSMA is the mandate to work with the States and our other partners to build a national integrated food safety system that will enable us to achieve our food safety goals more effectively and efficiently. We eagerly embrace these governmental partnerships in doing our work.

We also believe strongly in partnership with the food industry and our consumer stakeholders. Our partnership approach has been demonstrated so far by the extensive outreach we have done to all segments of the food safety community domestically and internationally, both before and after issuing the proposed rules that FSMA mandates. We have benefited enormously from innumerable public meetings, dialog sessions and webinars with individual groups and dozens of farm and plant tours, where my colleagues and I have learned firsthand how food safety can be achieved on a practical basis across the great diversity of our food system. We are committed to sustaining this partnership and dialog approach throughout the implementation of FSMA.

As you know, Mr. Chairman, and as you have already acknowledged, we have issued seven major rulemaking proposals mandated by FSMA, and when they are final, they will provide the framework for systematically building in prevention measures across the food system, again, produce safety, preventive controls, the things that you have pointed out.

I would be happy to answer questions about any of these rules, of course, but I want to highlight just very briefly some points about the proposals on produce safety and preventive controls which we published in January of 2013.

As you know, the proposed rule on produce safety would require farms covered by the produce rule, and it is a targeted set of farms, to follow certain standards aimed at preventing microbiological contamination of fresh produce. The proposal on preventive controls would require facilities to have a written plan in place to do modern preventive controls, have plans in place, verify that those controls are working. These proposals are grounded in practices that many in the food industry are already following, but as we seek to create a level playing field of standards through regulation, we fully anticipated that a number of challenging issues would arise, and that is why we have emphasized outreach and dialog and that is why we have received over 15,000 comments on the produce safe-

ty proposal and over 7,000 on preventive controls. As I say, we have learned a lot through this process. That is why in December we announced that we intend to publish and seek further comment on revised rule language regarding certain key provisions in the produce and preventive control rules on which our thinking has evolved. Through this process, we are confident that we can issue final rules that improve public health protections while minimizing undue burden on farmers and food processors.

We also recognize that FSMA will only be as effective as its on-the-ground implementation of the final rules after they are issued. Our implementation strategy includes partnering with other governments to ensure appropriate and efficient oversight and compliance but also a concerted effort prior to enforcement to facilitate compliance through education, technical assistance and regulatory guidance.

Now, before closing, Mr. Chairman, I must note the importance of finding the resources that FDA will need to implement FSMA in a way that achieves its important food safety and economic goals and meets the expectations of our many stakeholders. We have adequate resources now to issue the required regulations and conduct the mandated number of domestic inspections, and we will continue efforts to make the best use of the resources we have, but simply put, we cannot achieve FDA's vision of a modern food safety system and a safer food supply without a significant increase in resources. Last May, Secretary Sebelius submitted to Congress a report outlining the resources needed to adequately implement FSMA including resources needed to retrain FDA and State inspectors, provide training and technical assistance to small- and medium-sized farmers and processors, build the Federal-State partnership and, very importantly, implement the new import safety system mandated by Congress.

The import need is particularly acute, Mr. Chairman. We import 50 percent of our fresh fruit and 20 percent of our vegetables, and imported food shipments have increased from about 400,000 per year in the early 1990s to nearly 12 million today, but clearly, our resources have not kept up with this incredible expansion of food imports. The need to improve import oversight was demonstrated once again in 2013 by significant outbreaks of foodborne illness involving the hepatitis A virus linked to pomegranate seeds from Turkey and the cyclospora parasite linked to produce from Mexico. Congress was right in mandating a new import safety system, which is needed to protect consumers and provide a level playing field for U.S. producers and processors, but we cannot do what FSMA mandates without the resources it takes to build the new import system.

We are grateful, of course, for the resources we have been given through the 2014 appropriation process, which will be helpful in the near term, but I would also note that the President's 2014 budget request included a proposal for authority to collect two fees that would also go a long way toward helping us meet our food safety obligations under FSMA while also, we think, providing benefits for the affected industry and our State partners. One would address a registration fee for facilities that are registered with FDA. The second would be an import user fee, a minimal amount

per entry that would provide resources to fulfill the food safety purpose of FSMA and also provide greater efficiency and predictability for importers. We look forward, of course, to working with you on those.

I want to close, Mr. Chairman, and I appreciate the indulgence in going over the time, by just saying how gratified my colleagues at FDA and I have been by the strong expressions of support we continue to receive from our industry and consumer stakeholders and from the members of this committee for moving forward in implementing FSMA. It is important to get it right, and it is important to get it done, and with an undertaking of this complexity, we know there will always be challenging issues, but we are confident that this collaborative approach that we have taken, pursuing this approach, we can resolve issues in a way that is good for food safety and workable across our amazingly productive and diverse food system. I look forward to your questions, Mr. Chairman.

[The prepared statement of Mr. Taylor follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

**TESTIMONY OF**

**MICHAEL R. TAYLOR, J.D.**

**DEPUTY COMMISSIONER FOR FOODS AND VETERINARY MEDICINE**

**FOOD AND DRUG ADMINISTRATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**ON**

# IMPLEMENTING THE FDA FOOD SAFETY MODERNIZATION ACT

**BEFORE THE**

**COMMITTEE ON ENERGY AND COMMERCE**

**SUBCOMMITTEE ON HEALTH**

**U.S. HOUSE OF REPRESENTATIVES**

**FEBRUARY 5, 2014**

**For Release Only Upon Delivery**

**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]

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[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-111hhrg47797/html/CHRG-111hhrg47797.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*.

rule[10] 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.

Mr. PITTS. Thank you. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Mr. Taylor, as I said in my opening statement, I have been waiting for FDA's sanitary transportation rule for some time since we passed the Sanitary Food Transportation Act. I have continued to hear some real horror stories about drivers turning off their refrigerator units to cut cost, and I called on the agency to expedite its efforts to address these serious problems. Can you briefly comment on the agency's recent proposal and what it will do to ensure food is safely transported from its producer or manufacturer to our local retailers?

Mr. TAYLOR. Certainly, Mr. Chairman. We do consider the safe transport element of FSMA to be an important part of the farm-to-table prevention strategy. Our science tells us that this is not the highest risk part of the food system by any means. We have fairly limited experience in recent years with outbreaks associated with transport. There have been historically major outbreaks. The Schwan's ice cream outbreak in the 1990s made 220,000 people sick by virtue of inadequate sanitizing of trucks. But the rule that we have proposed under the FSMA mandate will ensure that there is clarity of responsibility among those who are shipping product, that is, who have produced a product and are seeking to have it shipped to a customer, those who are actually transporting the product and those who are receiving it, clarity of responsibilities for ensuring that the right practices are taken across that transport part of the food system including where it is appropriate and necessary to protect the safety of food that refrigeration is maintained.

And so we have focused in on the core elements that we think are important in transport. We think we have got a practical system that will provide us clarity of responsibility. Again, many in the industry are already doing these things but we will fill in, I think, importantly this part of the farm-to-table system.

Mr. PITTS. Thank you. There are a number of unique issues related to the inspection of seafood processing facilities and imports from abroad. Can you please comment on the various programs FDA has in place to oversee our global seafood supply as well as recent improvements made to these systems.

Mr. TAYLOR. Certainly, Mr. Chairman. Back in 1996, actually, FDA issued so-called HACCP regulations, essentially preventive control regulations for seafood processing facilities, both in the United States and overseas, for facilities shipping product to the United States, and this is the modern approach to preventive controls that FSMA has mandated for the entire food supply and that we are working to implement, and so we have a long history of implementing modern preventive controls for seafood. We do import 80 percent of our seafood, and so the oversight of imports is a crucial part of the system. The system includes responsibility for the importer to verify, have some verification from the foreign supplier that they are implementing modern preventive controls, but we also prioritize in our foreign inspection program seafood facilities because we do want to verify that these modern preventive controls are being implemented and we target facilities based upon information we know about where potential hazards might be.

We also have, under the existing law, the authority to stop product when it comes into the country. This is a reactive system, and it is not the prevention system that we will ultimately have when FSMA is implemented, but we have strong authority. We have used it frequently with respect to seafood to detain product from facilities or even from countries where we have repeated violations of issues like animal drug resides or other matters of concern from a food safety standpoint.

So we have a solid program. We will continue to work to improve it but it is based upon the modern principles that now FSMA is mandating comprehensively.

Mr. PITTS. Thank you. The committee appreciates the agency's efforts in this regard and is committed to ensuring that unnecessary and duplicative programs do not hamper such efforts. Provisions added to the Farm Bill at the last minute expanding the Department of Agriculture's catfish program would do just that. I agree with GAO and others that while doing nothing to improve safety, this program is a waste of taxpayer dollars and would increase compliance costs across the seafood industry.

Understanding the complexity of the issues involved and the diversity of those impacted, I appreciate the agency's extension of comments, particularly with respect to the produce and preventive control rules. Can you comment on whether the court-ordered deadline to finalize these major rules has hindered your agency's ability to continue what I consider an essential dialog with the regulated community?

Mr. TAYLOR. Mr. Chairman, we don't feel that the deadlines have hindered that dialog. The deadlines are a challenge, but we are organized and focusing our efforts to meet those deadlines. We believe we can do it. We think our ability to reopen the comment period for comment on some of the key issues of concern will advance the process, but we will have to be very efficient and work very hard to meet those deadlines, but we are committed to doing it.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman, and I want to thank you, Mr. Taylor, for coming here today. I know that Congress gave FDA a big job to do when we passed FSMA, so I wanted to ask you to give us a sense of the scope and diversity of the new responsibilities that FDA is directed to undertake in about a minute or so.

Mr. TAYLOR. Just from a practical matter, it is really about creating comprehensively a new system of prevention. It is a new food safety system beginning with what happens on farms where we have never regulated for produce safety before going all the way through processing and transport and then recognizing that we have to manage global supply chains, so it is an entirely new import oversight system. So it is a massive undertaking. If you just read the law and count up the deiliverables, as I think you indicated, it is a huge task and it is requiring us to mobilize everything we have got now and to figure out, you know, and be very clear about the resources that we will need to carry it forward to successful implementation.

Mr. PALLONE. Thanks. I touched in my opening statement, I said that CDC estimates that 48 million Americans get sick, 128,000

are hospitalized and 3,000 die each year from foodborne illnesses, and these numbers show that this is a serious problem that can be devastating for families.

Let me ask you two questions. What are the impacts on consumers who contract a foodborne illness and how will FSMA benefit consumers and reduce the burden of foodborne illness?

Mr. TAYLOR. Mr. Chairman, some people think that foodborne illness is just an upset stomach, and many of those 48 million cases are transitory illnesses, but they do add up to a big public health burden in and of themselves, but many foodborne illnesses are devastating, lifetime damaging experiences. People lose organ function. People's lives are changed forever and incurring not only great suffering on their part but medical costs, and then 3,000 people die. So it is more than a transitory stomachache.

And again, the whole idea here is to build in the practical preventive measures that can stop E. coli and salmonella and other pathogens that can make people sick from getting into the food system and doing that in the most practical but systematic way possible, and by doing that, again, we are not going to eliminate foodborne illness but we can substantially reduce these illnesses and benefit consumers. These illnesses are largely preventable, and I think what people expect is that we do everything we reasonably can to prevent them, and I think that FSMA is the mandate and the system to do that.

Mr. PALLONE. Well, I am going to get into the resources issue because you mentioned that, and that is obviously very relevant.

FSMA gives FDA many new tools to use to improve the safety of the food supply. However, I am concerned that you will have a hard time making full use of them without added resources. The agency's report to Congress last April on domestic capacity building to implement FSMA mentions there is a gap in funding needed to fully implement the law and it briefly discussed how the authority to generate new user fee revenues would be used for food safety, and as you know, the food safety bill that the House passed in 2009 did include facility registration and importer fees to increase resources.

Would you just comment on what the food-related fees proposed in the President's fiscal year 2014 budget would be used for if Congress gave FDA the authority to collect them, and how would the absence of user fee revenue affect the agency's ability to continue to implement FSMA?

Mr. TAYLOR. So there are two fees, as I mentioned. One is a facility registration fee. Those resources would be focused on improving inspection and being sure that our inspection force is trained and prepared to work under the new modern preventive system, so training for inspectors would be a big part of that. Those resources could also be used to support the Federal-State partnership. We think we can be more effective working closely with State partners who already conduct some inspections for us. They need their own training and capacity building.

The import fee would really be the key to building the new import system. We are mandated to establish this foreign supplier verification program requirement but that puts us in the position, which we want to be in, of auditing complex supply chain manage-

ment systems. We need a whole different training and orientation of a frontline workforce. We need staff to do that work in addition to actually checking product coming in at the port of entry, and then very importantly, Congress, I think, wisely mandates us to be much more present overseas, to work with foreign governments, to do more foreign inspections, to see that preventive measures are being taken offshore. So it is really building that new import system that the import fee would be crucial for.

Mr. PALLONE. All right. Thanks so much. I still have a few minutes.

The chairman mentioned the catfish, and I would like to know, has FDA found catfish to be a high-risk food and can you describe for us the system FDA has in place for fish and seafood safety and whether FDA has found that catfish pose unique or special risk warranting special oversight?

Mr. TAYLOR. Certainly, the reason we issued the HACCP rules, the preventive control rules for seafood, is because seafood, if not handled properly, can present concerns, but within the seafood universe, we actually think catfish is on the lower end of the spectrum of potential risk. It is not sold in a form that is ready to eat. Smoked product, for example, is more risky. It is not consumed raw, generally, and we don't have a history of outbreaks associated with catfish.

Mr. PALLONE. All right. Thanks again.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman, and welcome, Mr. Taylor.

So in the full committee and our various subcommittees, it is amazing how some things reoccur, so my discussion is going to be—I am going to use the term "recycling", but as we have found in other sectors, we force ink producers to throw away ink instead of bringing them back through the process because of rules and regulations. As we heard yesterday, we force electronic manufacturers to throw away their boards instead of recycling them because of rules and regulations.

So this is the first question. In the process of commodities that are already safe for human consumption that goes through the process in the front end, and let us just take barley that is going to go into production of adult beverage—beer. Then it goes through the process but then there is always obviously the remaining ingredients after the process has occurred. Many times that then is used in animal feed issues. Now, a concern is developing that if in this process then FDA then forces that end-use muck that has been used in animal feed to then go through another inspection process to see if it is safe for the feed processing and animal feed, then you will do the same thing that we did with ink and the same thing we do with computer boards. We will then add an additional burden in disposal and then we will take away a commodity product for food processes. That is a concern. Can you speak to that?

Mr. TAYLOR. Sure, Mr. Shimkus. We are aware of this issue, and of course, we have proposed a preventive controls rule for human food facilities and a preventive control rule for animal feed and animal food facilities based on the same principles that the law lays

out, but there are differences in the way in which human and animal feed need to be handled for safety purposes, so we have two separate rules. But they have to fit together and they have to work in a way that does not disrupt this practice. We are very aware of this relationship between human food and animal food production, and we don't see any reason from a food safety standpoint to disrupt that at all, and based on the comments that we are getting and will get on this, I think we can harmonize these rules and avoid the concern that you are raising. I am confident about that.

Mr. SHIMKUS. OK. You understand the concerns, and our basic premise is, if the entry point is safe for humans, understanding you have got to figure out the endpoint and the processes, but it should be safe for animal feed for the most part.

Mr. TAYLOR. Yes. And the system is all about being risk-based and it is about not duplicating effort, and so there are any number of ways in which we are being very careful to be sure that we are getting the control we need but not having duplicative controls.

Mr. SHIMKUS. But you don't know of any record in that process of animal feed through that processes has caused any human health indications? There has been no report to anybody that there has been any incident?

Mr. TAYLOR. I am not aware of it sitting here. If others are, we will put that in the record.

Mr. SHIMKUS. And I don't think there is either, and that is the point of the debate.

Mr. TAYLOR. Thank you.

Mr. SHIMKUS. I appreciate it.

Let me also then go to—there is a great deal of variability in food products and processes, as you know. Therefore, a successful testing program is tailored to a specific circumstance related to each product in manufacturing operation. How will the regulation be written to assure that testing is risk-based and not prescriptive, very similar to the other previous question but this is really just in the initial phase.

Mr. TAYLOR. That is very important. I think we all know from long experience that certain kinds of testing programs and certain kinds of facilities can be important to verifying the controls are working. Peanut butter processing facilities, for example, where salmonella in the environment can contaminate peanut butter and cause a significant problem. Most companies undertake so-called environmental monitoring testing of the environment to verify that the sanitation and other measures are preventing the presence of that pathogen.

But it is also well understood that those testing programs have to be based upon the particular risk considerations, the processing systems and the products in that particular facility. There is no one-size-fits-all solution, and I think if we are agreeing on anything across the board, one-size-fits-all doesn't work on any dimension really here.

Mr. SHIMKUS. I think that is what we find out in our committee, and going back to the hearing yesterday on another subject, risk-based is where we need to be, and really, the private sector, if you evaluate their testing processes and you find that it adequately does the test, the concern is, government will be prescriptive and

they will say test it this way where we know that the industry has already got a pretty good process of ensuring safety and efficacy.

Mr. TAYLOR. If I may, just really briefly, I mean we know there are firms that have invented the standard of care, if you will, or have programs that are in place and are doing the right thing and in fact go beyond what we would end up mandating. We have to have rules that are flexible enough to not disrupt those ongoing processes while also setting a standard of care that is clear and implantable by those who aren't there yet and who FSMA is intended to bring up to an appropriate standard. So that is the balance we need to strike in the final rules.

Mr. SHIMKUS. Thank you very much.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Mr. Matheson, 5 minutes for questions.

Mr. MATHESON. Well, thank you, Mr. Chairman. I appreciate the committee holding this hearing. I think this is a good thing for Congress after it passes a law to take a look at how it is being implemented. I think that is something we ought to do a lot of in Congress across all committees, so I do appreciate this hearing.

Mr. Taylor, I have heard some concerns raised, and this may have been covered a little bit before but I am going to ask you again anyway. I have heard concerns raised about the language in the proposed rule on the preventive controls. Some have raised a concern that the use of the phrase "reasonably likely to occur" in the rule is different than the Congressional intent, which would be "reasonably foreseeable" that is in the law, that is the term. Can you talk about these concerns, the validity of these concerns, what these different—you know, to me, these are two different sets of language, and I don't know want to get into semantics, but sometimes it matters, so can you talk about that, about what that means?

Mr. TAYLOR. Sure, and we don't need to go into a lot of detail to sort of get what is the central important point. It is one that we were just discussing. Concern really rises from folks whose systems are advanced, they are established, they are clearly achieving the sort of prevention that FSMA is about, and we want to be sure that we don't use language and rules that would create a concern about forcing change in those practices that don't make a practical difference for food safety, and we have had a lot of dialog with industry stakeholders, particularly on this point, and we think there is a way to solve this and manage this so that we achieve the purpose that I just recited. We need flexibility for them but a standard that we can implement and enforce where needed for those who aren't there yet.

Mr. MATHESON. So to the extent you have heard concerns raised about this, you are trying to work with stakeholders right now to figure out a way to——

Mr. TAYLOR. Absolutely. We have very active dialog. This is a solvable issue.

Mr. MATHESON. That is great.

The next question I would ask is, the law asks for an increase in the number of domestic food facility inspections. Do you have

any indication of how many inspectors that is going to take and what the costs are going to be for this?

Mr. TAYLOR. Well, I think one of the things that is fortunate is that with the increases that have happened over the last few years, we feel that we have the number of people we need to meet that domestic inspection frequency mandate, so that is a part of FSMA where we think we can hit the number. What we don't have is the resources right now to retrain and reequip those inspectors to work in this sort of modern preventive controls environment where we want to be focusing on the public health outcome and not just a checklist of regulatory requirements. So we need that, and then——

Mr. MATHESON. Do you have those resources, by the way?

Mr. TAYLOR. We don't have that, and that is the kind of additional funding that we need in order to implement FSMA successfully to really get the full modernization benefit that FSMA is about.

Mr. MATHESON. Do you have a sense about what that gap might be?

Mr. TAYLOR. I will stick with the request in the President's budget and it included about $225 million in fees, which would go a long way towards closing the FSMA funding gap. The total FSMA funding gap that Secretary Sebelius recited to Congress in the spring of last year was $400 to $450 million above our 2012 base. We took a step back in 2013. We took a step forward in 2014. We still have a sizable gap.

Mr. MATHESON. Do you plan to use third parties to conduct some of your inspections?

Mr. TAYLOR. No, sir. We will partner with State governments and other governmental partners on inspection. We do see the value of working to strengthen the private audit system that the industry has developed over the last number of years, and the law itself, as you know, mandates that we establish an accredited third-party certification program for certain import oversight purposes that are fairly narrow and targeted, but we would not ever think of private audits as a substitute for our inspection.

Mr. MATHESON. For the ones that are not domestic, for the ones overseas, how is that third-party system implemented so far? How is that going?

Mr. TAYLOR. The way in which Congress has prescribed that accredited third-party auditors be involved in certifying the safety of imports is in two situations. One is, as part of the so-called voluntary qualified importer program, which is the expedited entry system for people who are going the extra mile, that would include an accredited third-party audit of the foreign facility. We also have the authority to mandate an accredited third-party audit for particular high-risk situations, but those are the specific uses for which the accredited third-party audit is in the law.

Mr. MATHESON. All right. Well, thank you for your answers, and Mr. Chairman, I will yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the chair emeritus of the full committee, Mr. Barton, 5 minutes for questions.

Mr. BARTON. Mr. Chairman, thank you. I am going to yield my time to Mr. Walden of Oregon.

Mr. WALDEN. I thank the chairman emeritus, and I thank the chairman for holding this hearing, and Mr. Taylor, it is good to see you again. I have appreciated the meetings that we have had with you and your team and your openness to taking a look at how some of the ag practices actually occur on the ground and may be in disconnect with the original rules, and I appreciate your coming out to the Northwest and bringing your folks to meet with a lot of our growers out there, especially on the east side of my district with the onion growers who actually are having their annual conference about now and to witness firsthand how irrigation works and the kill step in growing onions and the safety of how they do it, so I was really pleased you were open, you listened, you pulled back the regs that would have been in conflict and moved forward, so I commend you for that, and I hope the science that our OSU lab produced out there on this issue involving onions was helpful. I sense that it was in your decision-making.

My question relates to, as you go about redrafting the rules and what interactions you might be having with farmers and ranchers out in the West, certainly in districts like mine, and as you write these new rules, obviously that continued communication is important to the extent it is allowed under your rulemaking process.

Mr. TAYLOR. Thank you, Mr. Walden. The trip to your district was just a great learning experience for all of us, and we appreciate the hospitality that you and your colleagues there showed us.

But yes, when we reopened the comment period and proposed alternative language on certain key provisions, there will be at that point an opportunity to have not only written comments but to engage directly with people who will have perspectives on what we have re-proposed, and we will be re-proposing on the water standard including the standard itself and the testing regime that we propose, so there will be interest, no doubt, in your community. We look forward to whatever dialog would be useful. And the research that is going on in Oregon at the University is helpful work, and we are collaborating closely there, and I think we can address the concerns that we heard about out there.

Mr. WALDEN. And as you know, there was some language in the Farm Bill that dealt with some of these issues around the rules in terms of the economics and I think in terms of the science as well. Obviously it is critical that we get a science-based set of rules that actually work in the real world. I know when I was out and met with our onion growers, toured around, as you and your team did at another time. They were just pointing out how from field to field you could have radically different readings for no real reason that is even manageable, and meanwhile I think one of the growers told me they have been growing onions there for a hundred years and never had an outbreak of salmonella, and they bagged I don't know how many millions of bag every year. I thought that was a pretty big sample size if you were going to do a statistical analysis of risk, and so I appreciate your pulling back on those rules. It is just essential whether it is there or our cherry and pear and apple growers or blueberry growers that we get this right and not upend them. And of course, they have concerns about imported foods, do

they meet the same ag practices we are putting on American farmers and we ought to be careful. None of us wants spoiled food. None of us wants the illnesses. I actually helped lead some of the investigations into Peanut Corporation of America but that was a case where they did things that were against the law to begin with, and they are paying a very severe penalty, as they should, for their actions. So we want to make sure we have got this balance right between safety of our food supply that allows for productive agriculture to continue in a way that works.

Again, I thank you for listening to us and actually coming out on the ground, and I hope that as we go forward with those rules that there will plenty of time for our folks that are going to have to abide by them to have full input.

Mr. TAYLOR. Absolutely. We are working toward the same goal, and we will get there by working together, so we look forward to that.

Mr. WALDEN. Thank you. Mr. Chairman, I yield back to the Chair.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the ranking member emeritus of the full committee, Mr. Dingell, 5 minutes for questions.

Mr. DINGELL. [Inaudible.] It is important and, as a matter of fact, urgent, and I am pleased that the subcommittee is conducting proper oversight of this important law. This is the way oversight should work. The Food Safety Modernizationn Act was a strong bipartisan response to the globalization of our food supply and to the numerous tainted food products coming in from abroad. It is clear that FDA needed new, innovative authority to ensure the safety of imported foods. It also needed money and personnel to do its job. FSMA was a significant step forward, but we have a lot of work left to do. The CDC estimates 48 million people get sick from foodborne illness each year. Furthermore, 128,000 people are hospitalized and 3,000, at least, die. Although we are not going to get these numbers down to zero, we must continue to focus on improving food safety in this country, particularly that which comes in from abroad. While FSMA represents a significant increase in authority for the FDA, Congress has only solved half the problem.

We also need to give FDA the resources it needs to fully implement FSMA and to create a proper, adequate 21st century food safety program.

Mr. Taylor, I request that you answer these questions yes or no. Does FDA have the resources in money and personnel it needs to properly implement the Food Safety Modernization Act? Yes or no.

Mr. TAYLOR. No, sir.

Mr. DINGELL. I would appreciate it if you would submit to us a proper survey of what you need in the way of money to accomplish this purpose.

The Obama administration's fiscal year 2014 budget request included $59 million in food facility registration fees and inspection fees, and $166 million in food import fees to help fund food safety activity. Does FDA continue to support user fees to pay for FSMA? Yes or no.

Mr. TAYLOR. Yes, Mr. Dingell.

Mr. DINGELL. Congress gave FDA a big job to do but clearly not enough money to do it right. I would note that the House-passed version of FSMA contained user fees that would have helped solve the problem, but this provision did not make it into the final version of the legislation. Many stakeholders continue to have concerns both about the timing and the substance of FSMA regulations. I would posit that these issues may not have been a problem if we had done the right thing early on and given the FDA the resources that they needed.

Today, we find FDA under court-ordered deadline to finish all FSMA regulations by June 2015. Do you have the money to do that?

Mr. TAYLOR. Yes.

Mr. DINGELL. You do?

Mr. TAYLOR. To get the regulations issued, yes, sir.

Mr. DINGELL. All right. Passage of FSMA was the product of collaboration between industry, consumer groups and the agency, and I think the industry deserves accommodations for the fine work they did on that matter from start to finish. I hope that this process will continue as FDA moves forward with the finalizing of these critical regulations.

Next question. Mr. Taylor, will FDA commit to working with all stakeholders in considering public comments as the agency works to meet the June 2015 deadline for issuing final regulations? Yes or no.

Mr. TAYLOR. Yes, absolutely.

Mr. DINGELL. Now, one critical part of FSMA is increased inspections of both foreign and domestic food facilities, and FDA will need to hire more inspectors to properly do the job, and I happen to think that we desperately need more inspection of foreign producers and more scrutiny and surveillance of foreign producers and others who enter the food supply chain. Is that a correct assumption?

Mr. TAYLOR. Yes, that oversight is important.

Mr. DINGELL. Now, FDA will need to hire more inspectors to properly do the job. Is that right?

Mr. TAYLOR. Yes.

Mr. DINGELL. And you are going to have to have some more for overseas?

Mr. TAYLOR. Yes. We have the resources for domestic but not for overseas inspection.

Mr. DINGELL. Does FDA have the resources to meet the hiring targets set by FSMA? Yes or no.

Mr. TAYLOR. Yes, for——

Mr. DINGELL. You do?

Mr. TAYLOR. No, no, no.

Mr. DINGELL. You do not have those resources?

Mr. TAYLOR. Those targets in the law, we do not have the resources to meet them.

Mr. DINGELL. I don't want the record obfuscated on this matter. Will you submit, please, a detailed response for the record including the resources you need and how many FTEs, or full-time equivalent employees FDA needs to hire?

Mr. TAYLOR. Yes, we will.

Mr. DINGELL. And how many do you plan to hire?

Mr. TAYLOR. Well, our plan will be the function of the resources we get, and we will lay that out in the response.

Mr. DINGELL. Submit for the record, if you please.

Mr. TAYLOR. Yes, sir.

Mr. DINGELL. FSMA also contains some exciting new authorities that are already in place and are protecting the American people including mandatory recall of tainted food products. That is a new authority to the agency. Is it working?

Mr. TAYLOR. Yes.

Mr. DINGELL. Does it need change?

Mr. TAYLOR. It works. We don't think it needs changed.

Mr. DINGELL. Has FDA exercised a mandatory recall authority under FSMA? Yes or no.

Mr. TAYLOR. Yes. We have initiated the process twice. The firms have wisely voluntarily recalled once we invoked the mandatory authority.

Mr. DINGELL. They didn't fight you on the recall?

Mr. TAYLOR. No, sir. That is the power of this authority.

Mr. DINGELL. Are you comfortable that the authority is sufficiently sweeping and adequate to carry out your responsibilities there?

Mr. TAYLOR. Yes, within the food part of FDA.

Mr. DINGELL. Food?

Mr. TAYLOR. Yes.

Mr. DINGELL. Now, you do not have the authority with regard to pharmaceuticals, do you?

Mr. TAYLOR. That is correct.

Mr. DINGELL. And how about other things like devices, knees, hips?

Mr. TAYLOR. You are leading me out of my territory, Mr. Dingell, but there are gaps in FDA's authority on the medical products side with respect to mandatory recall.

Mr. DINGELL. I want to thank you for this. I believe that mandatory recall is a useful tool in any emergency and should be expanded to the other areas that we have just been talking about in the agency's jurisdiction.

Now, FDA has a large task ahead of it, and as the agency works toward final implementation of FSMA, I urge the agency to move quickly during the rulemaking process while continuing to engage in a collaborative process with the stakeholders because working with the stakeholders will be the way that you will get their support, their wisdom, and the ability to do your job better.

Mr. TAYLOR. Thank you, sir.

Mr. DINGELL. Mr. Chairman, you have been most courteous in giving me extra time, for which I thank you.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the vice chair of the subcommittee, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. As I was listening to that exchange with Chairman Dingell, it took me back to the heady days when he took the gavel from Mr. Barton, and in fact, if you look back at that time, the budget for the Food and Drug Adminis-

tration was about $1 billion and today it is more than that. Is that a fair statement?

Mr. TAYLOR. Yes.

Mr. BURGESS. It is about two and a half times that amount?

Mr. TAYLOR. In budget authority, yes.

Mr. BURGESS. So——

Mr. TAYLOR. That is for the agency as a whole, not for the food side of things.

Mr. BURGESS. Correct. But even with the sequester, the Food and Drug Administration received from Congress an increase of nearly $100 million over the amount provided in fiscal year 2013, and in fact, you got several million dollars over the agency's budget request. Is that not a true statement?

Mr. TAYLOR. We got what we asked for on food safety to implement FSMA, yes.

Mr. BURGESS. OK. So nearly a billion dollars, $900 million, was targeted to the food and safety network. Is that correct?

Mr. TAYLOR. Yes, sir.

Mr. BURGESS. So Mr. Dingell was talking to you about the—he wanted some detail on the resources that you think you might need. I guess that means resources in addition to that $900 million was what he was asking for, but can you provide us the accounting of how the $900 million has been spent so far that was targeted to the Center for Food Safety and Applied Nutrition?

Mr. TAYLOR. We can do that. Just to be clear, that $900 million you are referring to is total funding for all food-related activities at FDA. We have certainly deployed a huge part of that to FSMA implementation but those resources also cover what we do in food additive regulation, in nutrition, dietary supplements, you know, a range of other programs that we are responsible for. That is not all for implementing the Food Safety Modernization Act, but we can certainly provide you that information.

Mr. BURGESS. Could you provide us that with a level of detail so we would be able to—the key here is discernment. Chairman Dingell asked you for what you might need in the future but I would like to know what is being given and what is being spent and how it is being spent currently.

Mr. TAYLOR. Yes, indeed.

Mr. BURGESS. Let me ask you, because he brought up the issue of foreign suppliers, the scrutiny of foreign producers, I think, was the terminology he used. How are you organized or structured to make certain that there is that fairness that he was talking about, that we are not discriminating against local producers that are advancing foreign producers at the expense of local producers?

Mr. TAYLOR. Sure. So the answer to that is being able to implement the full FSMA import toolkit that we have been given to create this new import oversight system. The foundation for it is the foreign supplier verification program requirement, which makes the importer accountable for having a plan through which they can document that they know where their product is coming from, their imported product, and they can verify in an appropriate way based upon risk that the proper controls have been implemented at the foreign supplier point. That private sector responsibility for supply chain management is the foundation for this new import system

and it is much more preventive and, again, reliant on industry. It will work, though, to the extent that first we can have people who are trained and we have adequate numbers of people to check that those systems really mean something, that they are not just words on a page, so verifying that those audit systems are working——

Mr. BURGESS. And I think that is the key because we certainly heard through hearing after hearing after hearing in 2007 and 2008 and on into 2009 about where the problems existed, and there were imports that were coming in that had no business coming in. Are we better prepared today to deal with those problems?

Mr. TAYLOR. Well, we are building a system that will enable us to be prepared.

Mr. BURGESS. But we are not there yet.

Mr. TAYLOR. No, we are not there yet. I mean, again, I think there is—you know, FSMA has stimulated a heightened recognition and reflects a heightened recognition as well across the food system that we need to be improving how we manage supply chains globally as well as domestically, but FSMA won't fulfill its purpose until we not only have the regulations promulgated but until we can actually verify that the system is working. And again, Congress——

Mr. BURGESS. My time is running out. What are the barriers to promulgating those regulations right now?

Mr. TAYLOR. It is just a lot of work, a lot of issues, but we are deploying the people to do that. You know, that is our priority, is to get those rules done.

Mr. BURGESS. But when this legislation was passed by Congress in 2010, the promise was that we were going to prevent these problems that had been happening with such alarming regularity that we were going to protect the American people, that the FDA had not been able to keep up with the effects of globalization but that was going to change. When can we tell people to expect that change we can believe in to have happened?

Mr. TAYLOR. FSMA will fulfill its purpose when we are able to implement it, and it is not just the rules. It is the ability to oversee the rules. So it is a process that over the next several years will have the benefit that you seek but it is not an overnight process to build a modern food safety system for this century.

Mr. BURGESS. Several years, meaning it could be a decade?

Mr. TAYLOR. I think it won't be that long before you will have rules in place and the ability for us to verify that those rules are being implemented if we get the resources.

Mr. BURGESS. I hope not, because a decade actually would be 2020. That would be the 10 years from the passage of the Food Safety Modernization Act.

Mr. TAYLOR. I understand. Yes, sir.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentlelady from California, Ms. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

Commissioner Taylor, I thank you for your testimony, and I am glad to be here today ensuring that the Food Safety Modernization Act is and continues to be as effective as possible. I understand that the FDA faces an immense scope of responsibility in imple-

menting the Food Safety Modernization Act. You mentioned that FSMA will only be as effective as its on-the-ground implementation, and I agree.

Agriculture is one of the primary economic drivers in my district, and so these issues certainly hit close to home. Food safety for fresh produce such as leafy greens is obviously incredibly important. As you may know, following an earlier food safety crisis in 2007, California leafy green growers, many of them that are in my Congressional district, took it upon themselves to raise the industry safety bar by creating the California Leafy Green Products Handler Market Agreement—a mouthful, LGMA for short.

Since its founding, LGMA has become a strong collaboration between government and farming communities. They incorporate science-based food safety practices and mandatory government inspections in an effort to ensure safe leafy green products. The LGMA has already been, for all intents and purposes, verifying the leafy green industry's compliance with food safety practices that meet or exceed the specific rules being proposed under FSMA. Obviously we all want to make the processes as efficient and effective as possible, ensuring high standards without creating unnecessary redundancies. I just met with the California Farm Bureau folks, a couple from my district, just now. This is very much on their minds.

So my question to you: Can you tell me what the agency is doing to collaborate with groups like LGMA in this process? How will FDA work with industry to verify compliance with the new FSMA laws?

Mr. TAYLOR. Thanks very much for the question. The Leafy Green Marketing Agreement is a real demonstration of leadership on that part of that industry, which has come about in response to some of the outbreaks that were very costly and disruptive for that industry, and the standards that they have put in place and that they monitor themselves are very positive and are standards that, as you say, will likely meet or exceed what the Federal standards will be, and we certainly, as we think about how we verify compliance with this broad range of standards, absolutely want to cooperate with and place reliance where appropriate on these private efforts to monitor and verify and demonstrate that their product is being produced in accordance with these standards.

So we meet with, we collaborate with the folks involved in the Leafy Green Marketing Agreement. It is a very positive part of progress on food safety, so we embrace it.

Mrs. CAPPS. So it is not like one person has the rules and the other person is trying to comply, but you are all in it together?

Mr. TAYLOR. Enormous dialog and recognizing that we want to capitalize on what leaders in the industry have learned and then, again, not disrupt those practices that are working just out of some——

Mrs. CAPPS. Let me just push this a little further. Not that I don't agree with what you are saying, but as you know, unfortunately, contamination in our food supply repeatedly has threatened the health of Americans over the years, and you mentioned how costly it is to the industry as well. These events have really initiated such fear in consumers, considering the safety of our food sup-

ply—the very food that is the best for us. So we need more of a win-win, and I think that is behind this effort here, a bipartisan effort, to enact the Food Safety Modernization Act.

Now, several years postenactment, how have we become more prepared? Do you think we are in a position where we could not just prevent but anticipate the next big outbreak? How will the FDA be more effective in dealing with the next big food contamination emergency?

Mr. TAYLOR. I think there are a couple of things. I mentioned already that I think FSMA is part of a process where we have been making progress in the private sector and through collaboration between government and private sector to put in place practices even as we anticipate FSMA being implemented, and that is one way in which I think we are hopefully making progress. We have also done a lot of work at FDA and with the CDC to be better at detecting outbreaks earlier. We have created a focused, specialized team at FDA to do early detection of potential outbreaks, to respond more quickly, and then importantly, to learn from outbreaks. And so we have investigated, for example, the cantaloupe outbreak that killed 33 people associated with Listeria in cantaloupe. We did an investigation of what the potential cause was, and then we have been out collecting additional data to inform the cantaloupe industry about measures that can and should be taken.

So there is a lot of work going on which will continue, even as we get the regulations in place and are able to verify that the practices that we are learning work are in fact being implemented comprehensively, not just by the leaders but comprehensively across the system.

Mrs. CAPPS. OK. Great. I will yield back.

Mrs. BLACKBURN [presiding]. The gentlelady yields back. Dr. Murphy for 5 minutes.

Mr. MURPHY. Thank you, and welcome here. We appreciate your testimony. It is very enlightening.

I am wondering, the CDC a couple years ago said that there was a reduced or different risk in foreign imported products versus United States. Does that difference still exist?

Mr. TAYLOR. You know, the data that could be quantitative about this are limited but CDC did report increases in significant numbers of outbreaks associated with imports. And so we know that food can be jeopardized, whether domestic or imported, but imports are very much a public health concern.

Mr. MURPHY. I am just curious then. Is there a difference in seafood, meats, fruits, vegetables? Any categories in terms of which are at higher risk, or does it vary?

Mr. TAYLOR. It varies across category, and again, CDC has put out the best data on that, and again, I don't have time to go into detail but we could provide that for the record.

Mr. MURPHY. I appreciate that. Also, there have been concerns that have been raised in some sectors in the public about genetically modified organisms, genetically modified foods. While some may have concerns of risk, are there potentials that you are going to explore in the future with regard to some modifications that would lead to reduced risk for foodborne illnesses among some of these?

Mr. TAYLOR. Regrettably, I am recused from working on matters related to genetically modified organisms, and so if you don't mind, we will——

Mr. MURPHY. That is fine. You had mentioned that you are taking steps to inform some growers, some products of actions that they can take to improve safety. I appreciate that. Are you also providing technical assistance or support to them in particular to help them comply with rules?

Mr. TAYLOR. That is a very important part of our strategy and our plan. Even well before the rules are final, we have created in collaboration with USDA and with the State departments of Agriculture the Produce Safety Alliance at Cornell University, which is all about developing training and technical assistance materials for small growers. So this is central to our strategy. Educate before you regulate is a mantra that many of us are using.

Mr. MURPHY. So you would have been working directly with some of the growers and food manufacturers, listening and communicating with them on those?

Mr. TAYLOR. Yes, through their organizations and directly working with them.

Mr. MURPHY. Thank you. When a product is linked to some sort of outbreak and consumer confidence plummets, in many cases the company that had nothing to do with the issue will see sales of similar products decline, even though they are not part of that. How does the Food Safety Modernization Act address this to prevent some single outbreak from crippling a whole sector of the agricultural industry?

Mr. TAYLOR. That is a very important point because that is why many people in the industry are supporting this so strongly because they can be affected by what others do. The fundamental thing, of course, is to prevent these outbreaks as much as we possibly can so you don't have the loss of consumer confidence and market disruption, and FSMA will contribute to that greatly.

The other piece, I think, is this effort to detect outbreaks more quickly. The sooner we can detect an outbreak and contain it, the less disruption there is, and so both of these things, prevention and response, work together.

Mr. MURPHY. Now, also in addition to what is being done with growers, food processors, manufacturers, distribution, grocery stores, et cetera, what is being done in terms of public information campaigns to help all of us and our households know what should be done at home in terms of food storage, food preparation, what should be looked for in products that could tip off ways that the food may be containing some sort of illness?

Mr. TAYLOR. That is a really important question, and both FDA and USDA have consumer education programs. They are fairly modest in scale. We work with the Partnership for Food Safety Education, which is a collaborative undertaking between industry, consumers and government. We need to do more on consumer education as part of the public health prevention system in our mind, and one thing that has happened over the last year or two has been an Ad Council campaign, for example, that has tried to reach consumers through the advertising media. But there is more to be done to really understand how consumer education can be done in

a way that does change behavior and reduce risk. We can't depend on consumers to solve the public health problem but they are part of the ability to minimize risk, and we want to work in that as well.

Mr. MURPHY. I hope so. I mean, I can't recall ever seeing an ad of any kind that talks about some of these issues with food safety.

Mr. TAYLOR. It is very limited.

Mr. MURPHY. And yet we are the last part there. Other than knowing, you know, if there is a bulging can, don't open it or eat it, or look at the date on something or what most people do is simply smell the milk, and if it smells bad, don't have it, but other than that—I hope that that is an area because that is an area of public outreach I think is essential for people to know that.

Mr. TAYLOR. Agreed.

Mr. MURPHY. All right. Thank you. I yield back.

Mr. TAYLOR. Thank you.

Mrs. BLACKBURN. The gentleman yields back. Mr. Green, 5 minutes.

Mr. GREEN. Thank you, Madam Chairman, and I thank the chair and the ranking member of the committee for this hearing today. Commissioner Taylor, I want to thank you for being here and for your patience with us.

I have a district in Houston, in fact, the Port of Houston, and so a few years ago I had the opportunity to be on the docks with not only FDA inspectors but other inspectors for our food safety, and in Texas, we have not only a number of ports that bring in but we also have a huge land border that brings in untold amount of foodstuff from Mexico. Ensuring that the roles are effective in protecting public health and supporting industry best practices is critical. I believe that two of the most contentious rules you are developing are those establishing prevention, preventive controls and produce safety standards. It seems to have taken a long time for FDA to release them, and in fact, it may only have been because of the court order that you were able to release them when you did, and since that release you have delayed the close of your comment periods and announced you may be re-proposing parts of each of them.

My question is, considering the foundation of these rules are for establishing a preventive food safety program, can you tell us why they have taken so long to develop their release? I would hope that the proposed rules in working with the stakeholders you realize you have gone back to the drawing board, if that is part of it. But like my colleague from Texas, Dr. Burgess, said, it has been 3 years since the law passed. Can you describe the process you have gone through to develop them including engagement of those stakeholders and explain what makes them so contentious and can you explain their importance to public health?

Mr. TAYLOR. Sure, sure, and I appreciate your impatience. I have experienced it myself, and we are all working hard to get this done as quickly as we can. We do think it is critical to get it done right. We are really laying the foundation for the next 50 years of successful food safety oversight in this country, and I think we do have enormous momentum with the seven proposals we have published since last January.

I think one reason it takes time is because these proposals do have to work together, first of all. It is like putting a puzzle together and there are a lot of complexities among the provisions, but also we can't lose sight of the fact, and this gets to the question of why there are—you know, we have had a very vigorous dialog with people with different points of view. We are building a new system that affects a lot of economic activity and a lot of actors in our food system, and so understandably, people have perspectives, they have information that they want us to consider, and we feel obligated to and we want to because it is how we will get a good set of rules that will work for the long term. So we feel good about the dialog we have had. We think the process has real momentum. We are working to meet the court deadlines and balance these two considerations of speed and ability to be sure everyone is heard and we have got the best possible rules at the end of the day.

Mr. GREEN. My other concern is improving foodborne illness surveillance. It is a critical part of the Food Safety Modernization Act. I have been told that foodborne illnesses are woefully underreported and that the quality of reporting varies dramatically by State. I would like to know what the FDA is doing and planning to do to improve reporting of the foodborne illnesses, and as part of your answer, could you speak to what the FDA and CDC are doing to improve capacity at the State and local level to detect and track outbreaks?

Mr. TAYLOR. The surveillance of foodborne illness, of course, is CDC's responsibility, and they are charged in FSMA with improving foodborne illness surveillance. As I indicated, we work very closely with CDC on the early detection of outbreaks but the ability to respond to outbreaks is very much a function of what State health department capacity is because most of the legwork in a foodborne illness outbreak is done by State and local health departments, and they have suffered their own budget cuts. So there is a real resource sort of infrastructure problem in our ability to detect and oversee and then estimate the frequency of foodborne illness, and again, CDC manages that part of the food safety system but we are dependent on it and place the importance on it as much as anybody.

Mr. GREEN. Like my colleague, our chairman emeritus, I am concerned about not having the resources to do your job, and is this delay for the last 3 years now, is that because of some of the lack of resources that Congress may not have applied?

Mr. TAYLOR. No, sir. I think the time it has taken is a function of the complexity of the process, and we have deployed our people and put great——

Mr. DINGELL. [Inaudible.]

Mr. GREEN. I would be glad to yield.

Mr. DINGELL. [Inaudible.]

Mr. GREEN. And I appreciate the Chair's patience. Sometimes some of us support a unicameral Congress instead of having two bodies.

Mrs. BLACKBURN. The gentleman yields back.

Mr. TAYLOR. Can I just clarify the point that I wanted to make about this? By redeploying people within FDA and the resources we have gotten from Congress, we can issue the regulations. You

know, we can put the rules on the books. Where we are lacking resources and where the fees would be essential, the additional resources, is in implementing the rules, and that is where we get the food safety and economic benefit if we implement the rules that are envisioned and intended to have this modern preventive system. And that is where we have the big funding gap for FSMA is the implementation of the rules once they are promulgated.

Mrs. BLACKBURN. OK. The time for the gentleman from Texas expired. I recognize myself for 5 minutes.

Mr. Taylor, we are all concerned about the implementation and what that structure would look like, and of course, a risk-based structure makes sense but I think that what we know is that 1 percent of the domestically produced commodities account for 95 percent of the illnesses, and those commodities should clearly be the focus of any risk-based system, and I think that part of our concern is why you have chosen to broadly regulate commodities that have not been associated with human foodborne illnesses.

Mr. TAYLOR. So let me give you a little bit of—this is in the produce context, I think, and——

Mrs. BLACKBURN. Yes, it is.

Mr. TAYLOR. And do I have to respectfully say I am not sure the basis for the 1 percent, 95 percent point, but I would be happy to have dialog about that.

There is no question that there are some commodities that have been more associated with significant outbreaks that we have been able to detect and that CDC has reported than other commodities. There is no question about that. One important point is that our ability, as we have been discussing, to detect illnesses and outbreaks is limited by lack of resources, so there is greater underreporting of illnesses that occur.

What food safety experts recognize and what Congress recognized in passing the law is that when it comes to produce, if you don't pay attention to the quality of the water, the safety of the water you put on the produce that people are going to eat or you don't pay attention to the basic hygiene of the workers handling the food, you know, if you don't pay attention to what is happening when fertilizers are added that can potentially be carriers of pathogens, you know, Congress identified these basic vectors of possible contamination and directed us to establish standards that are reasonably necessary to prevent the introduction of reasonably foreseeable hazards. So it is a prevention syndrome. It is not a response——

Mrs. BLACKBURN. Right, and I——

Mr. TAYLOR [continuing]. To outbreaks, you know, regime in FSMA. And so that——

Mrs. BLACKBURN. I appreciate that, but talking to my Tennessee farmers about the produce safety rule, they are very concerned with the lack of flexibility. Now, I was pleased to hear you tell Mr. Walden that you are going to do a revisit on the water rules because you do have to take into account the regional and the local water supply issues that are there, but I think it is important, and I wish that you all would consider the relative risk and the comparative benefits associated with regulating some of these individual commodities. I will tell you, some of the rules are a head

scratcher, and I will give you an example. Kale listed as a commodity and noted never consumed raw.

Mr. TAYLOR. We learned through the comment process, and so that——

Mrs. BLACKBURN. Well, I was going to offer to make a kale salad for you, so I think it is interesting, those are the things that you read and it causes you to wonder if those that are writing these rules have ever set foot on a farm or if they have ever been to a Farm Bureau dinner where everyone is bringing their favorite dish and enjoyed some of these wonderful items. So I hope that listening to the questions that we are asking that it points up some of the things that we need to be bringing to your attention.

Mr. TAYLOR. Sure.

Mrs. BLACKBURN. And through the comment period, we know that you are going to come up with some of these.

I think that another thing, before my time expires, that I want to highlight with you is the factors or standards that the FDA used to establish its list of covered or exempt produce. This is something that has been questioned is, how you all came about those and what list would be regularly reviewed. So just know that all of that is on our list and we are going to continue to conduct oversight very carefully, and with that, I will yield back the balance of my time, and Mr. Griffith, you are recognized for 5 minutes.

Mr. GRIFFITH. Thank you, Madam Chair.

Thank you for being here this morning. In the FSMA law, Congress specified that facilities should identify reasonably foreseeable hazards, but my understanding is, in the proposed rules, the FDA is using "reasonably likely to occur" in the proposed preventive controls use. This language is different from law and forces the food industry to shift from focusing on what will occur to what can occur. Does in fact FSMA use "reasonably likely to occur" as a basis to define the threshold for determining preventive controls?

Mr. TAYLOR. That is not the term used in the statute. It comes from our experience with HACCP preventive controls, but again, we have heard a lot about this issue and I think we have a way to address this.

Mr. GRIFFITH. OK. And I just have to point out that, you know, I would have got in trouble. I am not a food expert. I was a lawyer by training. But my law school professors hammered into us the big difference between the possibilities that an expert witness might testify to or may testify to, and the probability, which is a different thing, and I think that is what people are concerned about. Any of us could be hit by a meteor, they are out there, but that doesn't mean we need to be taking evasive action when I cross the street from this building to the next.

Mr. TAYLOR. Yes, sir.

Mr. GRIFFITH. Likewise, if there is a probability, I do need to be watching out for those cars that are coming down the road.

Mr. TAYLOR. Understood.

Mr. GRIFFITH. And so I do appreciate that.

Also I am concerned, I just want to make sure that I have got this clear that, you know, I represent a rural area of the country, and I want to make sure that all my small farmers aren't getting into any kind of headaches and hassles that would close them

down. It is my understanding that if you are a farmer who is growing fruits and vegetables and you are selling directly to the end-use consumer, that unless you have sales of $500,000 a year on average over 3 years, that you are not covered by these rules. Is that correct?

Mr. TAYLOR. That's correct.

Mr. GRIFFITH. All right, and I do appreciate that.

Likewise, for people that are canning vegetables, making jams, or manufacturing honey for farmers markets and local consumption, am I correct also that they would be exempt from the preventive control rules?

Mr. TAYLOR. If they have sales below that $500,000 threshold, yes, sir.

Mr. GRIFFITH. All right. Are there new requirements that these smaller farmers or the farmers who are selling right at their farm or at the roadside stand or at the farmers market that they would have to meet in order to be in compliance with FDA's implementation of FSMA?

Mr. TAYLOR. For produce growers who are exempt under this provision, the only thing they are required to do—this is by statute, by the law itself—is post information about their location so that their direct-to-consumer customer can come back to them if they have a problem.

Mr. GRIFFITH. OK. And I appreciate that. I also will tell you that I appreciated it very much in previous testimony when you said that you all recognized that you can't have a one-size-fits-all approach. That is very refreshing. A lot of people are concerned both about that and about folks getting carried away and suddenly we are shutting down the small farm operations, and your testimony has made me feel better about that, and I appreciate you being here, and with that, Madam Chair, unless somebody wants my time, I will yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you very much. I appreciate it. I was over at the other hearing.

Mr. Taylor, I just wanted to follow up on an earlier question, I believe Chairman Shimkus asked this, about food byproducts being used for animal food. In Florida, the citrus industry sells orange peels, as you know, and oranges that have fallen off the tree for animal feed. I think there are large environmental and sustainability issues that FDA may be overlooking.

If the proposed rule drives up the cost of byproducts converted to animal feed chain, many small and midsized manufacturers will abandon the production of feed ingredients and send the byproducts and waste streams to landfills. This increases the load on landfills and decreases the available products for animal food feed, thereby increasing the cost.

So my question is, will the FDA perform an environmental impact analysis before the final rule?

And again, I want to ask this as well: Can FDA quantify the benefits of their proposal?

Mr. TAYLOR. Sure. So with respect to the environmental impact statement, we are doing an environmental impact statement on the

produce rule, and so that will accompany and parallel the rulemaking process and we will have that before the final rule. But on the specific issue, it is not our intent—and we are going to work hard based upon input we received from the community to disrupt these established practices of byproducts of human food production going into the animal feed system. I mean, that is an important part for reasons you have recited of our food system, so it is not our intent and we don't think from a food safety standpoint that would be necessary or appropriate.

So this is the kind of issue that arises during the rulemaking where we get comments, and I think we will work to harmonize the produce and preventive control rules to prevent outcomes that just don't make common sense. I mean, we are guided by common sense here, and I think this is an issue that is very manageable within the FSMA regime.

Mr. BILIRAKIS. OK. Very good. Thank you. I will move on to the next question.

With regard to cybersecurity, the proposed rule would require all mandatory records to be made promptly available to the FDA upon oral or written request. Is that correct?

Mr. TAYLOR. Yes.

Mr. BILIRAKIS. OK. If the FDA requires these records to be submitted electronically and reviewed remotely, how will the FDA validate that the requests are coming from authorized representatives, and more importantly, can you guarantee that the system will be safe from hackers or leaks?

Mr. TAYLOR. So the first point is, it is a work in progress and we need to work with the industry to figure out how we exchange information in a way that is most efficient for our collective purpose of protecting food safety, and so this is something we have to do in dialog with the industry including with respect to electronic transfer of records.

To the extent that records are transferred electronically, we absolutely have to protect the confidentiality of records that are confidential business information, and we have a lot of experience doing that with conventional records within our food program. There is a lot of experience elsewhere in FDA with electronic submission of data and the drug approval system. So I commit to you, there is no lack of sensitivity to the importance of protecting confidentiality of data. We have a lot of experience doing it, and it is something we will work with the industry to be sure we do right in this context as well.

Mr. BILIRAKIS. Thank you. My last question, Mr. Taylor: Florida has a significant number of beekeepers, as do other States. The beekeepers and honey production industry, along with others, have been victims of various illegal trade schemes perpetrated mostly by Chinese exporters. As a result of these trade challenges, a lot of adulterated products, such as honey, have entered the United States undetected. While imports are the responsibility of Customs and Border Protection, I understand that, once adulterated products enter into the stream of the U.S. commerce, it becomes the responsibility of FDA. Is that correct?

Mr. TAYLOR. That is correct.

Mr. BILIRAKIS. OK. I would like to know what FDA is doing to combat economically motivated adulteration, FDA's proposed rule on "mitigation strategies to protect food against intentional adulteration" did not include economically motivated adulteration within that rule and FDA will address it under a separate regulatory scheme. My question is, Could you explain to me how FSMA changes FDA's enforcement authority with respect to economic adulteration, and how it will improve FDA's enforcement over economically adulterated products, such as honey?

Mr. TAYLOR. Good but complicated question. We will be addressing intentional adulteration for economic purposes in the preventive controls rule. It is a challenge to do that, because in that preventive controls framework, we don't want to require the processor to control that which can't be anticipated, whether it is reasonably likely to occur or probable to occur, regardless of the language you use. We have got to sort of focus on what we expect of processors. So we had the melamine in pet food problem a number of years ago. It was imports from China. You know, that sort of intentional adulteration for economic purposes where you have got a past history of that problem occurring we think can be addressed through the preventive controls rule, but there is a whole array of economic adulteration issues that are going to have to be addressable through other means as a practical matter, and so we do provide guidance about what is appropriate in certain products. We take limited enforcement action within our resources. If it is not a safety issue, it necessarily ranks lower in our priorities in terms of deploying our inspection and enforcement responses. But there are things we can do and have done, and we know the concerns in the honey industry and we have had dialog, and we look forward to working further.

Mr. BILIRAKIS. Just a follow-up, has FDA, is there a national standard, have they created a national standard as far as determining whether there is adulteration? If they have not, why haven't they?

Mr. TAYLOR. Well, there is not a national standard of identity that I think some people have asked us to establish that we have not done to date. There are standards and we have acted on if they are illegal pesticide residues or antibiotic residues, which sometimes happens in honey. We have taken action. We can take action under current law. We don't need any new laws or regulations to take action there. It is more a matter of being able to detect these and invest resources to do the enforcement actions.

Mr. BILIRAKIS. Are you in favor of creating a national standard?

Mr. TAYLOR. I think in concept, we see the usefulness of it. Frankly, it is a priority and resource challenge for us, and so we are looking at other ways to try to address this and again welcome working with the industry.

Mr. BILIRAKIS. I really appreciate it. Thanks for the testimony.

Mr. PITTS. The Chair thanks the gentleman.

Mr. BILIRAKIS. I yield back. Thank you.

Mr. PITTS. The Chair now recognizes the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you, Mr. Taylor, for being with us today.

I have a question about, as the rules are being implemented and the scope and the breadth of the rules, to me it is foreseeable that there may be some discrepancies, and I am concerned, and I hope you can expand on the process that can take place if a grower or producer is basically disputing or disagrees with inspectors' conclusions or the interpretation of the rules, will the FDA provide a centralized timely mechanism for those growers or processors to appeal the FDA? I don't even know. It may not have even gotten that far yet.

Mr. TAYLOR. Well, we are not to the point where we have rules that we are enforcing but we are very sensitive to the fact that in the produce arena, we are regulating on farms in a way we haven't done before, and so we know we have to be sure our people are especially trained to understand and work in the farm environment, and we have to be very careful, particularly in the early years, that we understand what the expectations are, we have communicated that to growers, and then we make consistent decisions when we do see problems, and so there needs to be a process to connect that person who is on the farm with the subject matter experts and others who can be sure we make good, consistent decisions. The Commissioner announced earlier this week some major changes in the way we work internally within FDA to link, you know, our headquarter centers and decision makers with our field force in a much more vertically integrated way to address this very issue of, do we have the right training, the right oversight and making the right, consistent decisions. So it is something we are very sensitive to as we look forward to implementing the produce rules.

Mrs. ELLMERS. Well, do you know, and are there plans for basic comprehensive or directive as far as an appeal process?

Mr. TAYLOR. Sure. We already have processes in the chain of command through our field organization but we think produce is going to require some special vehicles. Again, we are going to be implementing these produce rules in close collaboration with States, and in fact, we envision that it is the State agencies that would be the primary frontline interface with growers. We expect to be on farms actually to a very limited extent. We don't have the resources, and we think that the States have real advantages in their local knowledge and expertise. So we need to work with our State partners. We met with the National Association of State Departments of Agriculture just earlier this week and we are working hard with them to figure out how we will be prepared to partner with them to do this work, so there is a lot of work to do to put this implementing system in place.

Mrs. ELLMERS. So you do foresee it as a partnership rather than a jurisdictional issue? Because I know we have run into that problem before.

Mr. TAYLOR. It has to be. I mean, Congress has mandated that we have a national integrated food safety system, has said that we should work with State agencies on produce oversight in particular. We are working hard to build that system. That is the only way we will be successful, we think.

Mrs. ELLMERS. Thank you, Mr. Taylor. I yield back the remainder of my time.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Chairman, and thank you for coming today.

I have a specific question that has been brought up in my peculiar—not peculiar to my district—but my understanding is that the proposed rule would apply to facilities that manufacture, process, pack or even hold animal food so they would be required to register it as a food facility under 415 of the Food, Drug, and Cosmetic Act if they fit that category, my understanding is, so the question is distilleries. I know alcohol is exempted from this particular section but the byproducts, so they are not manufacturing food but they take the corn, they take the mash and do their formula and distill off the alcohol and then the remaining is actually good protein corn because they use the best corn in the world, and so farmers do buy that. And so the question is, would a distillery that sells their—or any, you can do an ethanol plant, you can sell their byproduct as animal food required to register under 415? And that is a concern they have.

Mr. TAYLOR. Yes, the registration requirement—I am turning to my colleague because I don't want to give you the wrong answer, and we know this is an issue in the FSMA implementation, but the registration requirement was actually established as a result of the Bioterrorism Act of 2002 and regulations FDA issued back then, but it is significant for FSMA because the requirement to implement preventive controls applies to firms that are required to register under the Bioterrorism Act, and so there is a lot of interaction there and complexity, and frankly, I will have to get back to you on whether the current provisions of our registration requirements apply to the distillery that is producing the byproduct that is going to animal feed.

Mr. GUTHRIE. Yes, they are selling the byproduct instead of to discard it.

Mr. TAYLOR. Understood. But again, I think it is an issue that has come up in the FSMA rulemaking: how does the preventive control regime for animal feed apply to just that sort of situation. So this is an issue we will have to resolve in a practical way and again, the whole goal here is to achieve the food safety goal without imposing regulation just for regulation's sake, so we will have to figure out what the right practical answer is to be sure that the animal feed safety issue is being addressed in the most practical way.

Mr. GUTHRIE. Yes, I know it is very specific, so your getting back to me is a fair very point.

Mr. TAYLOR. Yes, sir, we will do that.

Mr. GUTHRIE. Thank you.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Georgia, Dr. Gingrey, 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you very much for holding today's hearing. I would like to welcome our witness, Mr. Michael Taylor, from the FDA.

Mr. Chairman, I understand that our witness served yesterday as a panelist at one of the sessions of the 2014 National Associa-

tion of State Departments of Agriculture winter policy conference in Reston, Virginia, and the topic was very similar to what we are discussing here at this hearing.

During the Q&A portion of that session, my home State of Georgia Commissioner of Agriculture Mr. Gary Black pursued a line of questioning where he felt he received incomplete answers. I think it was just a lack of time, and I would like simply to follow up on that line of questioning, Mr. Taylor, if you don't mind.

When do you expect the produce and preventive control rules to be finalized?

Mr. TAYLOR. No later, based upon the current court order, than the end of June 2015. That is our current requirement legally, and we are working to meet that.

Mr. GINGREY. At the end of 2015?

Mr. TAYLOR. End of June 2015. June 30, 2015, is the current court deadline.

Mr. GINGREY. June 30, 2015, not the end of 2015. All right. Now, these are kind of yes or no questions, and we can go through them pretty quickly.

Mr. TAYLOR. Yes, sir.

Mr. GINGREY. Is the intent of the Food Safety Modernization Act to ensure enhanced safety of all produce, both imported and domestic, for American consumers?

Mr. TAYLOR. Yes.

Mr. GINGREY. Would you care to speculate what weight the law places on imports versus domestic produce production? Is it fair to say that it is 25 percent import versus 75 percent domestic, or is it equal?

Mr. TAYLOR. Well, I think it is the same goal. We need to have the same assurances about the safety of imported food that we have about domestic food. When I think about where the innovative breakthroughs and real shifts from where we have been historically in regulation are coming, the import system is very much novel. You know, we have experience with preventive controls in processing facilities in this country through meat and poultry HACCP systems, what we have done for seafood, but it is a big, new departure to hold importers accountable for managing foreign supply chains and to have FDA mandated to be much more present overseas. So imports are a big focus of the law. I would——

Mr. GINGREY. Excuse me, because I have to watch my time, but really again, yes or no, is it correct that the current proposed rule for produce is focused on domestic production?

Mr. TAYLOR. No, that is not correct. Those rules will apply to domestic and foreign growers who are shipping food to the United States.

Mr. GINGREY. When do you plan to offer a rule on imports and will that rule mirror the proposed rule for domestic production with respect to content and ultimate impact?

Mr. TAYLOR. So the proposed rule on produce safety applies to foreign and domestic growers. The proposal we published in the summer of last year on foreign supplier verification is the central rule mandated by FSMA for strengthening oversight of imports because that——

Mr. GINGREY. Let me cut right to the chase here. Can you assure farmers in Georgia and across the country that they will not be placed at a competitive disadvantage with importers once both the domestic and import rules are finalized?

Mr. TAYLOR. That is absolutely our goal, and if we get the resources to implement the import provisions of this law, we can achieve that goal.

Mr. GINGREY. Well, that is reassuring.

Mr. Taylor, last question, but it is a longer one. Are you familiar with what has been coined as the BASE—this is an acronym—approach for produce safety under the Food Safety Modernization Act that has been promoted by my State's department of agriculture? Are you familiar with that?

Mr. TAYLOR. Not the acronym but——

Mr. GINGREY. B–A–S–E?

Mr. TAYLOR. Yes.

Mr. GINGREY. BASE puts States in the best position to efficiently drive the program under Federal regulations, thereby keeping hopefully the FDA off of American farms. Do you believe that this approach has merit?

Mr. TAYLOR. Yes, and we are working—it is not that we will never be on farms but as I said earlier, we want to partner with State agriculture departments, health departments, those who are involved in produce safety at the State level to be the frontline, the primary frontline presence working with growers, overseeing growers and verifying compliance. That is absolutely the system that we are working to develop.

Mr. GINGREY. Well, again, that is quite reassuring, and as I conclude, for those that might not know, BASE, the B represents borders between countries, where Federal involvement in produce safety begins at the borders and the ports of entry. A represents the correct role for the FDA is to audit State programs. S represents standards set across the entire country, and lastly, E represents, and I think you just said that, Mr. Taylor, represents education for State regulators. BASE puts States in the best position to efficiently drive the program under Federal regulations, thereby hopefully keeping the FDA off of American farms.

So I am very pleased with your response, and I see my time has elapsed so I will yield back.

Mr. TAYLOR. Thank you.

Mr. GINGREY. Thank you, Mr. Taylor.

Mr. PITTS. The Chair thanks the gentleman. That concludes the questions of the members who are present. There are other questions that members may have that we will send to you. I hope you will respond promptly. I hope you understand, we have a couple of subcommittee hearings going at the same time so members have been in and out.

Mr. TAYLOR. Yes, sir.

Mr. PITTS. Thank you. And I remind members that they have 10 business days to submit questions for the record. They should submit their questions by the close of business on Thursday, February 20th.

Very important hearing, very important issues, very informative. Thank you very much, Mr. Taylor.

Mr. TAYLOR. Thank you, Mr. Chairman.

Mr. PITTS. We look forward to continuing to work with you.

Without objection, the subcommittee is adjourned. Thank you again.

[Whereupon, at 11:48 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Opening Statement of Chairman Fred Upton**
**Examining the Implementation of the Food Safety Modernization Act**
**February 5, 2014**

Today we examine recent efforts by the Food and Drug Administration (FDA) to implement the Food Safety Modernization Act (FSMA). We appreciate FDA's Deputy Commissioner for Foods, Mike Taylor, returning to the committee to speak on this important subject and the many complex aspects of the agency's ongoing rulemaking process. Ensuring the safety of our nation's food supply will always be a top priority of this committee.

While I applaud Mr. Taylor for his outreach to a wide array of individuals, communities, and companies who will be effected by these regulations, a great deal of work remains to be done to get this new framework right from the outset. FDA should continue this dialogue with stakeholders and thoughtfully consider each of their concerns before finalizing the proposals the agency has issued over the past year.

Food safety cannot be a prescriptive, one-size-fits-all approach. FDA must fully account for the diversity of our nation's local farmers, food manufacturers, and distributors. For example, I repeatedly heard concerns from farmers in Southwest Michigan that FDA's initial produce safety proposal did not take into account the unique water supply issues they face in our region. I am glad FDA is not rushing to finalize this rule and will be proposing new language for comment prior to moving forward. Local farmers must have a seat at the table.

Further, many of the food manufacturers I have met with from Michigan and elsewhere have already implemented innovative, risk-based safety programs that prioritize safety while increasing efficiencies and keeping costs down. FDA's preventative controls regulations must be written to promote these best practices and not force companies to take a step backwards in order to conform to a check-the-box mentality at FDA. In order for that to happen, it is critical that the agency's inspectors are trained accordingly.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

February 24, 2014

Mr. Michael R. Taylor
Deputy Commissioner
Foods and Veterinary Medicine
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Taylor:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 5, 2014, to testify at the hearing entitled "Examining the Implementation of the Food Safety Modernization Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, March 10, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 10 2014

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the February 5, 2014, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Examining the Implementation of the Food Safety Modernization Act." This letter provides responses for the record to questions posed by Committee Members, which we received on February 24, 2014. We apologize for the delay in responding.

If you have further questions, please let us know.

Sincerely,

Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

**"Examining the Implementation of the Food Safety Modernization Act"**
**Hearing before the Subcommittee on Health**
**Wednesday, February 5, 2014**

**Attachment 1—Additional Questions for the Record**

**The Honorable Joseph R. Pitts**

1. **The foreign supplier verification proposed rule is focused on the ingredient risk. We believe that industry should also be looking at supplier risk. Does FDA agree that industry should look at both ingredient and supplier risk when making decisions on how to allocate supplier verification resources?**

We agree that importers should consider supplier risks in determining appropriate supplier verification activities. The proposed rule on Foreign Supplier Verification Programs (FSVPs) acknowledges the importance of supplier risks in the requirement to conduct a compliance status review and in the requirement to consider supplier practices as part of the analysis of hazards. We are considering comments that we have received regarding the ways importers consider supplier risks as part of the risk analyses they perform to help them determine appropriate verification activities. We will take these comments into consideration when we address risk-evaluation issues.

2. **The auditing and recordkeeping requirements in the foreign supplier verification proposed rule is correctly focused on the source of the problem in foreign food plants. But FDA has no authority over foreign food plants, and therefore, will rely on holding food importers responsible. How will FDA verify that only safe food is being imported? How will FDA plan to expand import testing in a cost-effective and timely manner?**

FDA will continue to conduct inspections of foreign food facilities to assess their compliance with applicable regulations, including the preventive controls regulations, once those regulations are finalized and are implemented. The FSVP requirements provide additional assurance that imported food is produced in a manner consistent with U.S. food safety requirements. After the FSVP regulations become effective, FDA will begin inspecting importers in addition to our scheduled inspection of foreign food facilities, as part of our efforts to ensure that imported food is safe and meets U.S. standards. Importer inspections will become a component of the risk-based approach to food-safety-related inspections that the Agency is developing in accordance with section 201 of FSMA (section 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). However, our capacity to fully implement importer oversight will depend on the resources the Agency has to devote to such efforts. The President's fiscal year (FY) 2015 budget proposed an import user fee that would help FDA meet its import safety obligations under FSMA.

**3. FSMA specifically recommends that the FDA take advantage of the capacity and expertise of certified contract testing laboratories to effectively and efficiently expand import testing. What are the FDA's plans for third-party testing domestically?**

Establishment of the FSMA laboratory accreditation program and model standards through rulemaking to implement FSMA section 202 is important to the Agency. FDA's priority presently is finalizing the seven foundational preventive-controls rules to meet court-ordered deadlines. The timing of the release of the proposed laboratory accreditation rule is still under discussion by the Agency. When the proposed laboratory accreditation rule is released, there will be a public review and comment period as has been provided for other proposed FSMA regulations.

**4. In your testimony, you stated that "FSMA will only be as effective as its on-the-ground implementation." To date, what has FDA done to develop and implement a comprehensive training program for its inspection workforce to ensure FSMA is enforced effectively, uniformly and fairly at both the federal and state level? What are the agency's plans and timeline for inspector training moving forward?**

FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances—the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprouts Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm.*

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry compliance with the new prevention-oriented standards.

Finally, FDA's Office of Regulatory Affairs University (ORAU) offers an extensive course catalog of instruction, both traditional in-classroom and distance-learning formats. We envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances'

standardized curricula and ORAU regulator training. We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the alliances and others to begin conducting training before the compliance dates of the final regulations.

5. **Under the proposed rule for preventative controls, food facilities need to have "qualified individuals" write and implement their food safety plans. How is FDA planning to train its investigators so they know how to evaluate the merits of a facility's food safety plan from a risk based standpoint? Will FDA investigators have the same training as qualified individuals?**

We intend to train food safety staff throughout the Agency and the states, including subject matter experts, investigators, and compliance officers across FDA's Foods Program, and state food safety personnel who conduct inspections on behalf of FDA. FDA plans to develop and provide guidance and technical assistance for food safety staff including regulatory partners to develop an adequate technical understanding of the prevention-oriented regulations and how to conduct prevention-based inspections. FDA also intends to have technical experts available at the time of inspection to respond to questions from Federal and state field investigators about food safety plans.

6. **It is essential that FSMA regulations are enforced consistently from one region to another, and by both federal and state officials. What is FDA doing to ensure this happens?**

As mentioned previously, FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances – the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprouts Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm*.

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry

compliance with the new prevention-oriented standards.

Finally, we envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances' standardized curricula and FDA regulator training offered by our Office of Regulatory Affairs (ORA). We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the Alliances and others to begin conducting training before the compliance dates of the final regulations.

7. **FSMA does not provide FDA with authority to mandate submission of facility profiles or electronic/remote access to records. While the preventive controls proposed rule does not explicitly require submission of facility profiles or electronic/remote access to records, it does request comment on whether FDA should require these in the final regulation. Is FDA still considering requiring these in the final rule and if so, under what authority?**

We have received numerous comments expressing concern about the submission of facility profiles and electronic/remote access to records. We are evaluating these comments and considering whether there are alternative approaches to obtaining information in advance of an inspection that would improve the efficiency of on-site inspections or perhaps obviate the need for an on-site inspection in certain circumstances. We note that section 418(h) of the FD&C Act provides, in relevant part, that the "...written plan, together with the documentation described in subsection (g) [Recordkeeping], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request." Section 418(h) does not provide that the written request must be made during an inspection.

On June 26, 2013, the FDA Office of Planning's Risk Communication Staff (RCS) conducted a usability test and a focus group with industry stakeholders on the topic of voluntarily submitting food/feed facility profile information. In addition to the end user testing, RCS also conducted a focus group with the same industry stakeholders to assess the ability of individual facilities to gather the information requested, the time needed, and the cost to the companies for filling out the profile, the major barriers for industry participation, and expected benefits, and to identify alternative sources for the government in obtaining similar information. We are currently evaluating the results from these focus groups along with the comments to the proposed preventive controls rule.

8. **In the preamble to the preventive controls proposed rule, the FDA "tentatively concludes" that it is appropriate to apply Part 11 to FSMA electronically maintained records. Then, FDA asks for comment on whether there are circumstances that warrant not applying Part 11 requirements. FDA did not apply Part 11 requirements during the Bioterrorism Act rulemaking process because it would have required companies to significantly redesign and replace existing systems. Please explain why the FDA has taken a different position here in its "tentative conclusion," and whether the FDA intends to move forward with requiring compliance with Part 11 for FSMA records under all of the proposed rules?**

We have received comments expressing concern about the need to comply with Part 11 for electronic records. We are still reviewing and evaluating these comments and considering whether there are alternative approaches that reduce the burden on industry, while ensuring the integrity of electronic records and protecting public health.

9. **The preventive controls proposed rule requires that records be kept for at least two years. Is this requirement prospective—and therefore would only apply to records created after the effective date of the final rule?**

Yes, it is a prospective requirement. The records retention requirements would become effective on the applicable compliance date. In our proposed rule we indicated that it is reasonable to allow for one year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. We further indicated that it is reasonable to allow for two years after the date of publication of the final rule for small businesses and three years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA.

<u>The Honorable G.K. Butterfield</u>

1. **The FDA and food companies can agree that the timely sharing of information is important. However, we have all been reading about the danger of computer hackers and the theft of business and trade secrets as well as personal data.**

    a. **As the Agency considers the exchange of food safety records electronically, should we be concerned about the protection of confidential business information and trade secrets?**

    With regard to the protection of data, FDA adheres to the Federal Information Security Management Act (FISMA) to ensure that the appropriate levels of information system security controls are in place for the sensitivity of any given information.

**b. Can you guarantee that the FDA can secure its own data systems and prevent criminals—foreign and domestic—from stealing trade secrets?**

FDA continually updates its information technology security systems to ensure the safety and security of the information and data entrusted to the Agency.

**c. Could a data breach result in counterfeit products?**

We have no evidence that a situation such as this has occurred. As mentioned above, FDA adheres to FISMA to ensure that the appropriate levels of information system security controls are in place for the sensitivity of any given information.

2. **I represent a district that still has pockets of persistent poverty. Many of my constituents in eastern North Carolina struggle from paycheck to paycheck and some have been unemployed for some time. This question is about new rules required by FSMA. I favor regulation when and where it is necessary to protect the public's health and wellbeing. But it's important to remember that regulations come with a cost. Often those costs are passed onto the consumer in the form of higher prices.**

**Considering the amount of work the Agency has done, the work that needs to be accomplished and the work required to consider technical public comment, can the Agency assure this committee that the final rules won't unnecessarily impact consumers like some in my district who can least afford it?**

Food safety is a fundamental public health concern and a topic on which the public has high expectations. Unfortunately, one in six Americans suffers from a foodborne illness each year, with the Centers for Disease Control and Prevention (CDC) estimating that 128,000 Americans are hospitalized and 3,000 die annually from foodborne pathogens. Prevention of foodborne illness through a modernized food safety system is the goal of FSMA and the foundational rules proposed by the Agency. The cost/benefit analyses that have accompanied the FSMA rules issued thus far demonstrate significant public health benefits compared to costs. In general, these rules establish best industry practices, and many companies are already in compliance with many of the provisions. To assist industry in complying with the rules in an efficient manner, FDA is also allowing extended time for small and very small businesses to come into compliance. In addition, the Agency has formed Alliances to provide technical assistance and outreach to help industry understand and comply with the regulations. FDA is committed to protecting public health and ensuring food safety by promulgating rules that address the risk to consumers, without placing an undue burden on industry.

3. **Commissioner Hamburg distributed a memo on February 3, 2014. That memo outlined changes and modernization of the FDA. One of the biggest changes is moving the FDA to commodity-based and vertically-integrated regulatory programs.**

   a. **What was the impetus for the changes?**

   The growing challenges posed by a myriad of new responsibilities acquired through recent legislation, the pace of scientific innovation, and globalization were the impetus for change. In response, on September 6, 2013, Commissioner Hamburg charged the Program Alignment Group (PAG), consisting of senior FDA leaders representing all Directorates, Centers, and ORA, with identifying and developing plans to modify Agency functions and processes in order to best achieve mission-critical Agency objectives. In order for FDA to avoid duplication of function and effort and enhance FDA's ability to succeed in the future, the Commissioner felt it imperative that there be greater clarity and transparency about relative roles and responsibilities of the Directorates, the Centers, and ORA, as well as greater operational and program alignment among these organizations.

   b. **Do you think that the shift to commodity-based regulatory programs will improve FDA review and response times, particularly for drug and device applications?**

   While each Center has sole control over its application review processes and program alignment changes will not directly impact this activity, any overall changes to streamline Agency processes and create more efficient work flow can contribute to improved review and response times for drug and device applications.

   c. **Has the FDA set a deadline for when this transition should be complete?**

   The Commissioner directed the Directorates, Centers, and ORA to establish Action Plans for each program that will define with greater specificity the operational changes and decisions needed, as well as the processes for their implementation. The Action Plans are due to the Commissioner by October 1. Successful implementation of these changes will take time, commitment, continued investment and evaluation, and will likely occur over the next several years. Concurrently, ORA and the Centers will streamline management and review levels, where feasible, in order to enable FDA to take timely and appropriate action, avoid duplication, improve efficiency and enhance accountability.

**The Honorable Marsha Blackburn**

1. **I was one of 33 House members who wrote you last fall asking for an administrative fix to a language problem in the Food and Drug Administration Amendments Act (FDAAA) of 2007 affecting animal food ingredient approvals. It has to do with your agency's interpretation of language related to a statutory requirement you set regarding pet food ingredient "standards." Your response to our letter was that you are working on it, but you hadn't quite figured out what to do. What is the status of the FDAAA fix? When can we—and the industry—reasonably expect you to fix the FDAAA problem?**

To comply with the requirements of FDAAA section 1002, FDA intends to initiate rulemaking to establish definitions for animal food ingredients which are either generally recognized as safe (GRAS) or approved food additives for use in animal food. We anticipate that the regulation would apply to all animal food ingredients rather than only to pet food because we do not believe it would be practicable to separate pet food ingredients from other animal food ingredients.

**The Honorable Peter Welch**

1. **We understand from farmers that the cost of implementation of these rules may put them out of business. Are you certain your economic costs for compliance estimates are accurate?**

The estimates are based on the best data available to FDA at the time of publication of the proposed rules. We understand that, due to the limited amount of data, and because the estimates reflect average costs over broad size categories, the estimates may not perfectly reflect reality for every individual farm or facility. Wherever possible, we attempted to capture the variability across size and category and the uncertainty inherent in this type of estimation. We are already aware of public comments that will likely lead us to change the estimations for the final analysis.

2. **What role will the states play in implementing FSMA? Is there an opportunity to begin the implementation process now, in advance of the finalization of the rules?**

The states have a very important role in implementing FSMA, and FDA has already begun working on implementation with the states. FDA established several workgroups under the leadership of the FSMA Operations Team to plan the implementation of the final FSMA rules. Each workgroup includes representatives from the key FDA Foods Program components and one or more state representatives. The workgroups are already developing strategies for outreach, training, technical assistance, data collection, and inspections and compliance/enforcement. In order to operationalize FSMA, FDA will need to leverage the resources and efforts of others by working in partnership to create an integrated global food safety network that includes other government agencies (Federal, state, local, and foreign). To that end, FDA has already begun to work with its regulatory partners through the

Partnership for Food Protection to discuss data sharing needs with our regulatory partners to guide inspection work planning. States and other food safety counterparts will be vital partners with FDA to leverage resources to conduct inspections, particularly in the produce arena.

3. **Do you plan to construct an adjudication or conflict resolution process to address the inevitable conflicts between federal regulators, state regulators, and/or the regulated community? If so, will you describe in detail—or at least give a preliminary outline of—what that process would look like?**

ORA has analyzed the need and is initiating the process to establish an Ombudsman position and associated processes, whereby issues or establishment concerns raised in these inspectional communications may be escalated by the establishment or by FDA in a manner consistent with how disputes are processed by other FDA Centers and offices. As part of the FSMA implementation effort, FDA has acknowledged industry's request to consider dispute resolution processes that provide for confidentiality as well as for enhanced consistency across all regions and commodities and an improved global approach in light of the increased formal foreign presence. The possible ORA Ombudsman would address these goals as well as offer a process for resolving issues that arise outside of an inspection.

4. **FSMA was designed to ensure a level playing field between domestic and imported foods. Can you assure Congress that domestic and imported foods will be treated equally?**

FSMA envisions a preventive controls framework to modernize food safety and help ensure the safety of domestic and imported foods. To establish this framework, FDA has proposed seven foundational rules. Rules such as the preventive controls for human food and animal food rules and the produce safety rule would apply to both domestic and imported foods. To provide additional oversight of imported foods, FSMA also mandates the implementation of Foreign Supplier Verification Programs (FSVPs) by food importers. Specifically, FSMA requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in a manner consistent with FDA's preventive controls and produce safety requirements, where applicable. In addition, FDA has issued a proposed rule on accreditation of third party auditors, a program that, when established, will provide a way to obtain certifications for foreign facilities and food under specified programs. The goal of the suite of FSMA proposed rulemakings is to ensure a level playing field for domestic and imported foods. It should be noted that to ensure adequate oversight and fully implement FSMA, the Agency will need additional resources as proposed in the FY 2015 President's Budget.

5. **We have heard that you have said we will need to educate before we regulate. How do you plan to implement this goal? What is your time line?**

FDA has funded three Alliances to develop training to help educate industry on how to

comply with the requirements of the preventive controls for human food and the produce safety rule. Each of the Alliances has a website on which they have posted informational materials about the Alliance and its activities.

The Food Safety Preventive Controls Alliance (FSPCA), developed in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), is a broad-based public/private Alliance consisting of key industry, academic, and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training, and outreach program to assist companies producing human and animal food in complying with the preventive controls regulations. The FSPCA will also be a repository for up-to-date scientific and technical information on hazards and preventive controls for foods. The core curriculum will be finalized shortly after the publication of final preventive controls rules for human and animal food. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

The Produce Safety Alliance (PSA) is led by Cornell University, and involves FDA, the U.S. Department of Agriculture (USDA), state food and agriculture departments, and two national industry trade associations. The PSA will produce a standard on-farm training manual and curriculum and plans to offer courses to deliver the training. The PSA is developing a training protocol with state and Federal regulators to help ensure uniformity in inspections. It will also be a repository for up-to-date scientific and technical information, including a compendium of produce hazards. The training will be finalized shortly after the publication of the final rule on produce safety. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

The Sprout Safety Alliance (SSA), developed in cooperation with IIT IFSH, is a partnership of Federal/state regulators, academia, and industry experts who are developing a core curriculum, training and outreach programs for stakeholders in the sprout production community to enhance the industry's understanding and implementation of best practices for improving sprout safety, and requirements for sprout producers in the produce safety rule. Content development will be complete in 2014 and will be followed by review and refinement and additional pilot training sessions with industry. The training will be finalized shortly after the publication of the final rule on produce safety. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

**6. Will you please explain how the agency will fix the "farm" definition so that it includes many activities that are regularly part of farming but that, as proposed, triggered the "facility" definition?**

We have received many comments related to activities conducted on a farm that are considered part of farming by farmers, yet trigger the requirement for a farm to register with FDA as a facility. Many comments expressed concern that activities such as packing or holding produce from a farm they do not own would subject them to requirements of the proposed preventive controls rules. Some of these issues predate the

proposed FSMA regulations. We are still reviewing comments on this topic. We are planning to publish revised language on key provisions of the produce safety and preventive controls for human food proposed rules affecting small and large farmers, including provisions affecting mixed-use facilities.

**The Honorable Michael C. Burgess**

1. **FDA's budget appropriations have grown from $1 billion to over $2.5 billion in the last seven years. Despite last year's sequester, FDA received from Congress an increase of $96 million over the amount provided in FY 2013 and $3 million above the agency's budget request. Of this $900 million was targeted to the food safety work of the Center for Food Safety and Applied Nutrition (CFSAN).**

   **The Administration's proposed FY 2014 budget for FDA included a proposal to impose a food facility registration and inspection fee to fund agency activities related to FSMA. While maintaining the safety of the U.S. food supply is the highest priority for both Congress and the FDA, I am concerned about how the Agency is using the funds that have already been allocated for food safety. Will you provide documentation and accounting for the $900 million that was targeted to the CFSAN?**

The $900 million you reference was for the Center for Food Safety and Applied Nutrition (CFSAN) and related field activities in ORA for FY 2014. Congress has provided additions to FDA's base budget for food safety in the amount of $138 million from FY 2011 through FY 2014. Those funds were used to replace staff who were lost during earlier budget reductions as well as to begin the process of implementing FSMA. A compilation of some of the most important uses to which those additional funds were allocated is outlined below.

**Funding History**

When FSMA was enacted, the FDA foods program was just rebounding from a decline in resources and expertise. In 2003, FDA's headquarters food center, CFSAN, had 950 scientists and other food-oriented staff. Various budget reductions in the 2000s had reduced the staffing level at CFSAN by 20 percent (to 750 people).

In 2010, food safety rose to the forefront of Congressional attention with enactment of FSMA and changed how food in the United States would be regulated. The new Act was passed in response to a cascade of food safety problems in the 2000s that sickened millions of Americans, reduced consumer confidence in the safety of the food supply, and cost farmers and the food industry untold dollars in lost sales, recalled products, and legal liability. Congress responded with additional funding for the FDA food safety program and over the next four years provided FDA with over $138 million in base funding. It also provided a one-time increase in FY 2013 of $37 million to support FSMA implementation.

With these new resources, FDA has strengthened its food safety program in a variety of important ways:

Began the development of new prevention standards – FSMA directs a massive paradigm shift for food safety, from reacting to food contaminations that have already occurred to focusing on preventing such problems before they affect consumers. With the new funding provided, FDA has been able to design, develop, and propose for public comment the seven foundational regulations that will govern this new paradigm. FDA has held numerous public meetings to ensure thorough involvement by stakeholders in the creation of these rules and to ensure a transparent rulemaking process. Just to illustrate the extent to which FDA has gone to ensure transparency in the evolution of these rules, the following example is offered. In support of the intentional adulteration proposed rule entitled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration," FDA has conducted three FSMA public meetings strategically located across the domestic U.S., 16 rule overview/listening sessions to both national and international stakeholders, and two listening sessions requested by stakeholders with specific topics of concern. A FSMA Fact Sheet specific to the intentional adulteration proposed rule was posted on FDA's website as well as a "Frequently Asked Questions" document to inform and assist stakeholders.

Met public and Congressional expectations for increased domestic food inspections – A key direction by Congress in FSMA is that every domestic facility deemed to be "high risk" must be inspected at least once in the five year period following the date of enactment of FSMA, and at least once every three years thereafter. With the new resources, FDA developed and released in March 2012 information on how it would apply the High-Risk definition to food facilities resulting in an increased inspection rate. Using these criteria, FDA met that target in FY 2013 and is now inspecting every high-risk domestic food facility once every three years.

Increased oversight of imported foods – As with domestic food inspections, FSMA directs FDA to increase efforts to help ensure the safety of food imports, which arrive at U.S. ports in over 12 million shipments each year. With the increased funding provided by Congress in FY 2011-2014, FDA has:

- Exceeded its target of import inspections by more than 10 percent (to almost 200,000 examinations by 2013);
- Increased inspections of foreign food facilities from about 350 in 2010 to 1,400 by FY 2013;
- Completed seven comprehensive assessments of foreign regulatory systems to determine if they provide the same safety protections as FDA and, with New Zealand, FDA has negotiated the first systems-recognition arrangement;
- Expanded FDA's foreign offices in some of the largest food-producing countries of the world, including China and Mexico; and
- Created the first regional training center, in Southeast Asia, aimed at building aquaculture producers' regulatory capacity and to address widespread problems

with imported seafood from Asia.

Developed state programs – Continued its efforts to assist the states through grants, contracts, and cooperative agreements to build their capacity as partners in the U.S. food safety system and be active partners in the prevention focus of FSMA and major contributors to the management of foodborne outbreak responses.

- Provided funding for 40 states to help them meet the Manufactured Foods Regulatory Standards; and
- Provided funding for 31 states to upgrade their public health laboratories.

Created three "Alliances" to help affected industries adopt new prevention standards – The new funding enabled FDA to magnify its investment by embracing a strategy of creating alliances that provide education, training, and technical assistance for industry and government officials. The Preventive Controls Alliance, the Produce Safety Alliance, and the Sprout Safety Alliance will tremendously help producers, especially small and medium-sized businesses, comply with the new prevention rules once they are completed.

Began a program of "risk analytics" – FSMA directs FDA to adopt risk-based regulations and compliance strategies, and FDA has used its new funding to initiate that effort, which will, over time, enhance the Agency's ability to focus on the highest risk foods and food facilities as well as better prioritize and utilize its own resources.

Conducted the Product Tracing Pilot Project – As required by FSMA, FDA has designed and conducted pilot efforts to determine how tracing of food can be carried out most effectively and efficiently. Included in this are examinations of the data that need to be collected by industry and government, ways to connect data to various points in the supply chain, and the rapidity with which government can receive data on contaminated food.

The examples above comprise some of FDA's most significant accomplishments as a result of increased funding over the past four years, but the Agency also made many other important achievements of smaller scope, such as:

- Updated, expanded, and improved the facilities registration system, which now includes over 193,000 domestic and foreign food facilities;
- Completed a final regulation on administrative detention of contaminated food, which provides a means through which FDA can hold adulterated or misbranded food and prevent it from reaching the marketplace, thus further enhancing FDA's ability to ensure the safety of food for the U.S. consumer;
- Developed a plan to help foreign governments build their capacity to better oversee food that might be exported to the United States;
- Established the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), an integrated Federal-state laboratory initiative to improve identifying and analyzing chemical and microbiological contamination of animal feed;
- Researched pathways by which foods become contaminated and how to prevent such contamination; for example, FDA developed a new rapid method for

detecting Salmonella and a new testing protocol for paralytic shellfish toxins;
- Executed a pilot project to utilize handheld analytical tools at ports of entry;
- Published a draft guidance for industry on Salmonella testing;
- Updated guidance for industry on eliminating seafood hazards in fish and fishery products; and
- Increased the Centers' compliance staffs to assist in the review of the cases resulting from the increased inspections.

2. **FSMA directs FDA to write new regulations for facilities that manufacture, process, pack, or hold human food. Facilities are required to maintain a written food safety plan and comply with the Preventive Controls rule, which includes specific food allergen controls.**

**a. How will FDA execute these preventive controls for allergens?**

FSMA requires a facility to identify and evaluate known or reasonably foreseeable hazards and lists allergens as one of the hazards facilities would need to consider. In the proposed preventive controls rule for human food, FDA proposed to require the implementation of preventive controls for hazards that are reasonably likely to occur and included food allergens as chemical hazards to be considered by facilities. We proposed including food allergen controls as preventive controls for facilities that handle major food allergens. We also proposed to require that food allergen controls include procedures, practices, and processes employed to ensure protection from cross-contact and for labeling of finished food to ensure allergens were declared on the label. In addition, we proposed to clarify in several provisions of our Current Good Manufacturing Practice requirements that protection against allergen cross-contact (inadvertent incorporation of an allergen into food) is required. FDA has been requiring facilities to address food allergens for a number of years and will continue to assess the control of food allergens during inspections.

**b. Will there be thresholds or standard levels?**

In December of 2012, FDA opened a docket to gather data and information related to the possibility of conducting a risk assessment related to food allergen thresholds. We have completed a detailed analysis of the comments submitted to this docket. We are also actively assessing the publicly available data in the published scientific literature on levels of sensitivity in the allergic population. Based on these inputs, we will use a risk assessment-based approach to determine if the data support establishing practical thresholds for any or all of the major food allergens. We will make a draft version of any risk assessment available for public comment before the document and results are finalized. We are aware of the public concern about the consequences of establishing such thresholds and will consider those concerns in making any final determinations.

3. **In the FSMA proposed rules, the FDA has proposed requiring submission of facility profiles with hazards and controls information as well as providing FDA with remote access to company manufacturing and related records. It is clear that the statute allows the FDA to access company record during the course of an on-site authorized inspection.**

    a. **Will you describe what statutory authority the FDA has in FSMA to require companies to provide FDA with remote access to company manufacturing and related records?**

    The proposed preventive controls rules require that records be made available upon oral or written request. It does not explicitly require a facility to send records to the Agency rather than making the records available for review at a facility's place of business. FDA requested comment on whether the proposed rule should be modified to explicitly address this circumstance. We note that section 418(h) of the Federal Food, Drug, and Cosmetic Act provides, in relevant part, that the "...written plan, together with the documentation described in subsection (g) [Recordkeeping], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request." Section 418(h) does not provide that the written request must be made during an inspection.

    b. **What additional information does FDA feel it needs to obtain through remote access to records that it could not obtain during an on-site inspection?**

    The information that would potentially be submitted is the same as what we would obtain during an inspection. As we noted in the preamble to the preventive controls rule, information in a food safety plan is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. Having information in advance of an inspection could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. We indicated that facilities would benefit from our advance preparation through interaction with better-prepared investigators and potentially reduced inspection time. Further, such advance record access could obviate the need for an on-site inspection in certain circumstances.

    c. **I am concerned that this additional regulatory burden and time-consuming process does not provide a commensurate benefit to overall food safety. How do you propose companies prioritize these additional activities over the usual activities that directly enhance food safety?**

    In our proposed preventive controls rules, we proposed that the records for part

117 be made available to an authorized representative of the Secretary of HHS upon oral or written request. We did not propose to require facilities to submit records electronically, but asked whether we should do so. We have received numerous comments expressing concern about the submission of records electronically. We are evaluating these comments before making a decision and will consider whether such requirement will impose a burden on industry that is not commensurate with food safety.

**The Honorable John Shimkus**

1. **Is it true that finished product testing may not be identified as necessary in a facility's food safety plan based on the relevance for the facility, food, and information from other verification activities but under the proposed Preventative Controls rule those products would be subject to mandatory finished product testing?**

The proposed preventive controls for the human and animal food rules would require that a facility verify that its preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. We did not include requirements for finished product testing. We did, however, acknowledge that product testing programs, when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. In appendices to the proposed rules, we provided our current thinking on the role of and need for product testing as well as some of the factors a facility should consider in establishing a product testing program. We agree that finished product testing may not be identified as necessary in a facility's food safety plan, depending on the food, the activities of the facility, and the nature of the controls. Our discussions in the proposed rules noted that finished product testing plays a very important role as a verification measure in ensuring the safety of food, *when implemented appropriately in particular facilities*. (Emphasis added.) We are evaluating the many comments on this issue.

2. **During your testimony, you noted that "certain kinds of testing programs ...can be important" in food safety systems, while stating that it is "well-understood that those testing programs have to be based on particular risk considerations." The Committee agrees that testing should be risk- based and that a "one size fits all" approach will not work. Although the FDA did not provide proposed testing language on which industry could comment, would you agree that prescribing specific testing for all possible variables is not practicable?**

Yes, we agree that testing for all hazards in all foods is neither practical nor necessary. As noted above, we believe that testing can be an important tool in a modern food safety system, particularly as a verification procedure under specific circumstances.

3. **In your opening statement, you said the Agency "intends to publish and seek comment on revised rule language on key provisions of the Preventive Controls rule... on which our thinking has evolved." I believe it is important for the FDA to seek additional comment from stakeholders on specific regulatory language that was left out of the initial proposal. Will this revised proposed rule allow for an academic discussion and response to detailed testing, supplier verification, and economic adulteration rules?**

In December 2013, FDA announced that it intends to publish revised proposed rule language in summer 2014 on key provisions of the produce safety and preventive controls for human food proposed rules affecting small and large farmers. These provisions include water-quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms.

Though we did not include specific requirements for environmental monitoring, finished product testing, or supplier verification programs in the proposed preventive controls rule, we did acknowledge that such programs, when implemented appropriately in particular facilities, could be used to verify the effectiveness of preventive controls and ensure the safety of incoming ingredients. We provided our current thinking on the role of and need for these types of programs in appendices to the proposed rules. We received many comments on these issues, including comments that requested an opportunity to comment on draft codified language in advance of a final rule. We are considering these comments and options to allow comment on these issues while maintaining our commitment to move swiftly to final rules.

With regard to provisions on economic adulteration, in FDA's proposed rule on intentional adulteration related to acts of terrorism, the Agency stated that before we decide to finalize provisions on economically motivated adulteration, we plan to provide new language and an analysis of costs associated with these provisions, and to seek comment. The Agency remains committed to allowing this opportunity for comment.

4. **FDA inspectors and investigators will need to be well educated in how to properly audit food safety systems. Historically, investigators have primarily inspected food facilities for physical evidence of hazards. Under the proactive nature of FSMA, FDA personnel will need to undergo a paradigm shift. They will need to be effective in understanding and evaluating the effectiveness of a facility's food safety system and they will need to evaluate through records review and physical inspection, whether the facility is complying with that system. Please provide a timeline for the Agency's implementation of a comprehensive training program for FDA inspectors, including state and local partners.**

FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with

state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances – the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprout Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm.*

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry compliance with the new prevention-oriented standards.

Finally, FDA's Office of Regulatory Affairs University (ORAU) offers an extensive course catalog of instruction, both traditional in-classroom and distance-learning formats. We envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances' standardized curricula and ORAU regulator training. We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the alliances and others to begin conducting training before the compliance dates of the final regulations.

5. **The Committee is concerned that the final rule may establish costly testing requirements that focus resources away from the most critical food safety activities. How will you ensure the final rule should provide that the necessity, location, and frequency of pathogen testing in the processing environment and on equipment, including product contact surfaces, is based upon the risk of the product, process, and hygienic status of the production environment, as well as risk information provided from other verification activities?**

In our proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," we did not include specific requirements for environmental monitoring but we acknowledged that such programs, when implemented appropriately in particular facilities, could be used to verify the effectiveness of preventive controls when contamination of food with an environmental pathogen is reasonably likely to occur. We provided our current thinking on the role of and need for environmental monitoring and some of the factors a facility should consider in establishing such a program in appendices to the proposed rules. Environmental monitoring programs should be based on the risk associated with the product and process, as well as the nature of the controls applied in a facility. We are evaluating the many

comments on this issue.

6. **During the hearing, you noted that the Agency is working with industry to "figure out how to exchange information," stating that there is "no lack of sensitivity" to the issue of protecting confidential business information. Viewing facility records is most meaningful when it is done within the context of an on-site inspection. Does the Agency plan to require access to information outside the context of an inspection? If electronic records access is necessary, what security measures does the Agency plan to put in place to prevent unauthorized release of confidential business information?**

We have received numerous comments expressing concern about remote access to records and the need to protect confidential business information. We are evaluating these comments and considering whether there are alternative approaches to obtaining information in advance of an inspection that would improve the efficiency of on-site inspections or perhaps obviate the need for an on-site inspection in certain circumstances. FDA currently collects information during inspections that companies consider to be confidential business information. We take our obligation to protect confidential business information seriously; FDA has Freedom of Information personnel throughout the Agency responsible for handling requests for information and for adherence to laws and procedures regarding the maintenance of confidentiality of non-public information. In addition, FDA has in place all of the appropriate encryption and firewall tools necessary to safeguard the confidential business information and trade secrets entrusted to the Agency.

7. **FSMA limits FDA's ability to mandate auditor reporting to Reportable Food Registry conditions and narrow situations where third-party auditors must be accredited under the FDA Third-Party Auditor Accreditation proposed rule. Will other audits, including consultative audits, be subject to reporting requirements to FDA? If so, under what circumstances?**

Section 307 of FSMA (21 U.S.C. 384d) establishes requirements for: (1) audit reports; and (2) notification to FDA when an auditor "discovers a condition that could cause or contribute to a serious risk to the public health." With respect to audit reports, FSMA section 307(c)(3) requires submission of reports of regulatory audits (conducted for purposes of food or facility certification to FDA) but not reports of consultative audits that would be conducted under FDA's proposed accredited third-party auditor program. FSMA section 307(c)(3) states that such consultative audit reports would be available to FDA only under section 414 of the FD&C Act (21 U.S.C. 350c), which gives us access to facility records if we have a reasonable belief that an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA).

With respect to "notification" of a condition that "could cause or contribute to a serious risk to the public health" under FSMA section 307(c)(4), we note that the statute does not define "serious risk to the public health" nor does it give examples of such conditions.

Rather, FSMA section 307(c)(4)(A) (Risks to Public Health) describes notifiable conditions as ones that "could" cause or contribute to a serious risk to public health, which suggests to us that the scope of this provision is broader than SAHCODHA circumstances. As explained above, FSMA section 307(c)(3) on audit reports specifically cross-references section 414 of the FD&C Act (21 U.S.C. 350c), but Congress did not use the SAHCODHA standard in describing the types of conditions that could cause or contribute to a serious risk to the public health and that must be reported to FDA under FSMA section 307(c)(4)(A). While we believe Congress intended the standard for notification under FSMA section 307(c)(4)(A) to be a different standard than SAHCODHA, in the proposed rule we invited comment from the public on how to interpret this standard.

**The Honorable Leonard Lance**

1. **The Committee is aware of and encourages the FDA's work with the cosmetics industry to develop a new regulatory framework to insure safety of personal care products while allowing innovation in product development. Will any proposed new regulatory requirements involve new revenue sources to the Agency?**

The President's FY 2015 budget requests new legislative authority to require domestic and foreign cosmetics manufacturers to register with FDA and pay an annual registration fee. The product, ingredient, and facility information submitted with registration would expand FDA's information about the industry and better enable the Agency to develop necessary guidance and safety standards. With these additional funding resources, FDA would be able to conduct priority activities that meet public health and industry goals.

FDA worked hard with the cosmetics industry last year to produce an agreement with industry on a detailed framework for legislation that established a regulatory scheme to protect consumers from risks associated with cosmetics. That framework included the concept of user fees. Unfortunately, the cosmetics industry has reconsidered the earlier agreement and we received a new proposal from them that would weaken FDA's current ability to take action to protect consumers from dangerous cosmetics. Industry's new proposal is unclear on the issue of new revenue sources. However, as noted above, the President's FY 2015 budget requests a cosmetic safety user fee.

2. **In my judgment, a key element of proposed new regulations, and an important part of a new regulatory framework, would be national uniform requirements. Does FDA support having national safety standards for cosmetics?**

The detailed framework that FDA and industry agreed on last summer included the concept of national uniformity on certain aspects of cosmetic regulation. States would have been preempted from taking action against cosmetic ingredients that FDA had found safe and would have been prohibited from establishing different requirements for registration, cosmetic listing, adverse event reporting, and good manufacturing practices (quality controls) from those of FDA. These limitations on State authority made sense in the context of significantly enhanced authorities for FDA to strengthen

the Agency's ability to protect consumers from dangerous cosmetics. Unfortunately, the proposal we received from the cosmetics industry in early 2014 would weaken FDA's current ability to take action against unsafe cosmetics. Through sweeping preemption provisions that, to our knowledge, are unprecedented in Federal legislation, this new industry proposal would also almost completely eliminate states' authority to protect their citizens from unsafe cosmetic products and ingredients, including thousands of ingredients FDA has not reviewed and has no resources to review. It would also remove basic state enforcement powers, such as inspection and recall authority. We believe that these sweeping preemption provisions could endanger public health by preventing states from taking action on safety issues that FDA may not be able to address.

3. **For years, the Agency has been asked to establish safety levels of ingredients, such as for lead in lipstick. A lack of action in this area results in consumer confusion and regulatory uncertainty for manufacturers. Will the Agency provide the Committee with a timeline for completion of safety level determinations under the proposed new regulations?**

The framework for new cosmetics legislation that FDA and industry agreed on last summer and the proposal FDA has received from industry in early 2014 differ dramatically in this area. The industry's proposal would require FDA to undertake a very resource-intensive and burdensome process requiring two separate rulemakings before FDA could establish limiting levels on either an ingredient or a contaminant (such as lead in lipstick). It is difficult to estimate how long this process might take, but we believe it would be substantially longer than the process outlined in the framework agreement.

**The Honorable H. Morgan Griffith**

1. **The Food Safety Modernization Act uses the term "reasonably foreseeable," but there are concerns that FDA may use the term "reasonably likely to occur" (RLTO) to define a threshold for determining preventive controls. The proposed RLTO standard lends itself to regulatory rigidity and perhaps absurdity. During the hearing, you stated that there is "a way to solve this and manage this" concern so that those facilities with advanced food safety systems do not have to change their already effective practices. How does FDA plan to address this concern, and when can the Committee expect a successful resolution?**

In the proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," we proposed that the application of preventive controls would be required in cases where facilities determine that hazards are reasonably likely to occur. We have received many comments related to the use of the term "reasonably likely to occur." Comments expressed concern that if we use this term as the basis for determining the need for preventive controls, then either all preventive controls will need critical control points (CCPs) or people will be confused by the term being different in this rule from the seafood and juice Hazard Analysis and Critical

Control Points (HACCP) rules. Comments have also expressed concern that this approach would require existing food safety systems to be revised. We are still reviewing comments on this matter.

**The Honorable Gus Bilirakis**

1. **Currently, over 200 Food and Drug Administration (FDA) regulations incorporate food ingredient standards the United States Pharmacopeia (USP) publishes in the Food Chemicals Codex (FCC). FDA from time to time updates these references, and the Agency has also worked closely with USP on important issues including adulteration of food ingredients (e.g., glycerin). In the hearing, FDA stated that a national standard of identity is useful, but FDA was limited due to resources. Would FDA be willing to work specifically with USP and stakeholders on the issue of economically-motivated adulteration of honey, to help protect its integrity and see if an appropriate national quality standard could be developed and placed in regulation?**

FDA believes that such collaboration may be helpful to us in identifying ingredients that may be sources of economically motivated adulteration in honey and will strongly consider working with USP in this area. Regarding the establishment of a standard of identity for honey, FDA has concluded that the establishment of a standard of identity for honey would not aid the Agency in its enforcement efforts or help ensure industry compliance. The Agency currently has authority under the FD&C Act to take enforcement action against adulterated or misbranded food products, including honey. In fact, FDA has acted to prevent adulterated honey from being distributed in the United States. A standard of identity is not a prerequisite for enforcement actions against food products that are adulterated or misbranded. On April 11, 2014, FDA issued draft guidance on the proper labeling of honey and honey products that advises firms on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded under sections 402 and 403 of the FD&C Act.

**Attachment 2—Member Requests for the Record Raised During the Hearing**

**The Honorable John D. Dingell**

1. **Please submit a survey of what you need in the way of money to properly implement the Food Safety Modernization Act.**

FDA cannot achieve our objective of a safer food supply without a significant increase in resources. As you know, the FDA Food Safety Modernization Act (FSMA) has instructed FDA to overhaul its food safety program, with major new directions, such as:

- Shifting food safety from an old, antiquated system of chasing after problems once they occur to a new focus on prevention
- Better integrating Federal efforts with state and local food safety systems
- Implementing an entirely new import oversight program that relies on importers having more responsibility regarding the foods they bring into the United States
- Increasing both domestic and foreign inspections, especially in facilities producing foods at high risk of contamination
- Modernizing and streamlining the food importing process so as to enhance trade in safe food.

Some of these efforts are well underway. For example, resource increases provided by Congress in earlier years have permitted FDA to meet the Congressional mandate to inspect domestic high-risk food firms more frequently and to greatly increase inspections of foreign facilities.

As reflected in FDA's FSMA Section 110 report last year (*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm351868.htm*), CBO estimated that the Agency would need an estimated $400 - $450 million in funds added to its FY 2012 base by FY 2017 to implement FSMA. FDA has received approximately $138 million in increases towards FSMA implementation thus far. The FY 2015 President's Budget proposes an additional $253 million to support FSMA implementation.

The urgency of receiving adequate funding is that FDA is under court-ordered deadlines to issue key final rules in late 2015 and early 2016, which means FDA must be equipped to begin sound inspection and other oversight activities to ensure smooth and effective implementation in late 2016 and 2017. Without immediate investment in the advance preparation that is essential for sound implementation of the FSMA rules, implementation will be disrupted and delayed to the detriment of public health, consumers, and the food industry.

Below is a detailed summary of how FDA would use the additional funding to implement FSMA.

**Domestic**

Center Technical Staffing and Guidance - FSMA directs FDA to undertake its most complex and challenging effort ever to produce the rules and guidelines under which the food industry will ensure safe food and feed production and FDA investigators will inspect. Those new standards must have a strong basis in science, be the product of the best technical expertise available, and be the result of continuous discussion with stakeholders. Additional funding would be used to recruit knowledgeable experts at FDA who can ensure that the new prevention standards and guidelines are based on the best science and intimate knowledge of industry practices. These experts are also essential to support FDA's compliance force in properly overseeing implementation of the new standards. FDA would also support collaboration with industry, academia, and state extension services to ensure that their concerns are heard, that their advice is solicited and utilized, and that the rules are the most cost-effective solutions achievable. Implementing these activities is urgent because the rule and guidance development are underway, and final rules must be submitted to the *Federal Register* for publication on a court-ordered timeline.

Education/Technical Assistance for Industry - The shift toward preventing food contamination directed by FSMA creates a need among many farmers and processors – and especially small producers – for technical assistance to facilitate their implementation of the new standards. For example, approximately 36,000 fruit and vegetable producers could be subject to the proposed produce safety rule, and approximately 40,000 food (including animal feed) facilities could be subject to the proposed preventive controls rules. Many of these firms are expected to seek training, advice, and technical assistance to fully understand and comply with the new requirements. Further, many additional farms and facilities that would be exempt, not covered, or subject to modified requirements are expected to seek assistance. FDA believes that it should expend substantial financial resources to further the food safety objective by providing guidance and working with Federal, state, and local partners assisting industry in coming into compliance. In addition to providing guidance, FDA would provide financial support to state agencies and public-private-academic collaborative entities, such as the Produce Safety Alliance and the Preventive Controls Alliance. Without these activities, industry will not get the help it needs to successfully implement the new requirements, and the movement toward safer food production will be markedly delayed.

Inspection Modernization and Training - FDA inspectors are currently trained to inspect food manufacturers using a compliance model focused on finding evidence of hazards. The new food safety paradigm will be focused on preventing hazards through a system-based approach and on ensuring consistency among all inspections. This new paradigm involves a major reorientation and retraining of almost 1,700 inspectors, compliance officers, and other staff involved in food safety activities in fundamentally different approaches to food safety inspection and compliance. To accomplish this in time, training in the new prevention and systems approach must begin in 2015, with further technical training continuing into 2016 and beyond after the FSMA rules are finalized. FDA has also committed to move toward more targeted, risk-based, and efficient inspection models, which will require better data

about facilities, new IT systems to identify and track risk, and methods for assessing and tracking inspection efficiency and inspector competency. Those systems also need to be in place at the time inspections begin in 2016. Thus, FDA would not need more inspectors, but rather the means to make its current inspectors efficient and effective under the new inspection and compliance approach.

National Integrated Food Safety System - The states are projected to conduct over half of the domestic facility inspections required by FSMA. Building state capacity to coordinate effectively with FDA is a central tenet of FSMA and is needed to ensure that states are prepared to conduct these inspections using the same standards and methodologies as FDA inspectors. States will need inspector training, greater information sharing capacity with FDA and other states, state laboratory coordination, and inspector certification programs. Like FDA's own retraining effort, those processes, which will be carried out mostly via FDA grants to 40 or more states, must begin in 2015 if the states are to be prepared when industry becomes obligated to comply with the new regulations starting in 2016.

Risk Analytics and Evaluation - One key element of FSMA is the vision of future regulatory action being focused on the degree of risk posed by a given food. So FDA is developing new tools that will provide the information needed to focus decisions and resources on areas of greatest risk to public (human and animal) health. This includes new tools for ranking risks, prioritizing program activities based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution. For example, these new tools might better inform FDA about which foods are most vulnerable to which bacterial contaminants or where FDA should invest its research efforts to most effectively identify how to reduce contamination of food. As a result, this will improve FDA's productivity in all areas, including research and standard setting, inspections, and technical assistance to industry. In addition, the FY 2015 budget requested $977,000 in antimicrobial resistance funding to support data collection and evaluation needed to monitor and assess the impact of FDA's initiative to limit the use of antimicrobial drugs in food animal production.

**Imports**

FSVP Implementation - The Foreign Supplier Verification Program created by FSMA will transform import safety screening by requiring importers to develop supplier verification plans to help ensure greater food safety before food or feed is sent to the United States and examined at the border. This shift will have wide effect for both FDA and food importers, given that there were approximately 88,000 consignees receiving food shipments last year. To be successful, FSVP will require a substantial regulatory development process, staffing and training within FDA to enforce the regulation, and extensive training and technical assistance for importers. Without the means to make FSVP implementation successful, FDA could fall short of meeting FSMA's goals.

Overseas Presence and Partnerships - One of FDA's best opportunities for return on investment is in helping foreign governments better ensure the safety of food and feed before it is even shipped to the United States. FDA has been implementing that concept in three ways: placing staff in foreign offices, increasing the number of foreign inspections, and

developing partnerships with its counterparts overseas. Some of those efforts are focused more on technical assistance, such as helping other nations improve their regulatory systems and upgrade their public health laboratory methods and training. Others are more sophisticated, such as working with more developed countries on "systems recognition," a process by which FDA will determine whether another country's food and feed safety system provides protections comparable to those in the United States and, thus, that food from that country will be of a lesser concern when it is exported to the United States (allowing FDA and industry to focus their import screening efforts on areas of higher risk). The first such analysis was completed with New Zealand in 2012. One with Canada is currently being negotiated, and others may be initiated in the future.

Private and Public Audit Enhancement - FSMA encourages the use of "auditors" to help food and feed importers successfully meet their requirements for better protecting food. Some of those auditors will be certified by FDA as part of a FSMA-mandated system for giving expedited entry for importers who meet the highest standards. All are part of a growing global system of food protection that is focused on helping producers and importers meet modern food and feed safety standards by the United States and other countries. A modest investment by FDA in working with industry to improve the training and performance of those auditors will pay dividends many times over in safer food and feed.

Port of Entry Streamlining - Food importers are increasingly communicating that FDA's screenings have posed challenges for them. Much of that is due to the exponential increase in food and feed imports in recent years, to almost 12 million shipments this year, while the number of border inspectors has remained static. Importers seek improvements to FDA procedures, such as more staff on duty during the busiest periods, a "help desk" to resolve delays, and better FDA information systems to identify the riskiest imports for better targeting. FDA is willing to provide those services, as they will not only assist importers but also enhance the Agency's ability to detect and deter contaminated food and feed being offered for importation into the United States.

**2. Please submit a detailed response describing what resources you need to meet the hiring targets set by FSMA and how many full-time equivalent employees FDA needs and plans to hire.**

As described in more detail in the previous response, FDA estimates that receipt of funds in the amounts requested in the FY 2015 President's Budget would significantly close the gap toward a goal of an additional $400 million to $450 million in funds added to its FY 2012 base by FY 2017. The President's FY 2015 budget estimates that 390 FTEs would be hired with the appropriated dollars and user fee funds. These hires would be a significant step in performing the work needed to create the import oversight system, provide technical assistance to industry and FDA inspectors in real time, and train federal and state inspectors. Additional full-time equivalents may be needed in future years to fully implement FSMA, but the FTEs anticipated in the President's budget would be a significant resource for FSMA implementation in the near future.

**The Honorable Tim Murphy**

1. **A couple years ago, the Centers for Disease Control said there was a reduced or different risk in foreign imported products versus the United States. Does that difference still exist? Is there a difference in seafood, meats, fruits, and vegetables? Any categories in terms of which are at higher risk, or does it vary?**

CDC has indicated in recent publications that outbreaks overall decreased in 2009-2010, but noted that preliminary information indicated an increase in outbreaks associated with certain imported foods (seafood and spices) for the same time period. However, CDC also noted that importation of foods was increasing over the same time frame. FDA's draft spice risk profile also noted evidence of increased contamination with certain pathogens in spices compared to other imported foods. However, CDC has also indicated that none of the reporting is over a long enough time period to establish a trend.

Overall, foodborne illness continues to be a significant problem in the United States. Unfortunately, one in six Americans suffers from a foodborne illness each year, with CDC estimating that 128,000 Americans are hospitalized and 3,000 die annually from foodborne pathogens. Prevention of foodborne illness through a modernized food safety system is the goal of FDA, particularly through implementation of FSMA, which contains provisions to address risk from both domestic and imported foods.

