Update on Implementation of the Food Safety Modernization Act

Delivery by Michael Taylor, Deputy Commissioner for Foods, before the Food and Drug Law Institute, Washington, D.C.

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Opening

It's a pleasure to be here at FDLI to talk about what is going on in the Foods Program and specifically about the Food Safety Modernization Act. Of course, we have a lot of other things going on, but implementation of the FSMA is in the center ring.

As you can imagine, this is a huge undertaking. But it's a welcome challenge to build a new system of food safety oversight that looks at the food system as a whole and marshals the efforts not only of FDA but of government at all levels and actors throughout the food system to improve food safety. And it is a powerful, positive thing that Congress has told FDA to create this system.

I'll focus on how we're approaching implementation, but first it's important to review how we got FSMA and the key FSMA principles that will guide implementation.

Unique Consensus and Coalition

We must not lose sight of how important consensus and coalition-building were to FSMA becoming law.

Consumers and the food industry forged a consensus that constantly responding to outbreaks and conducting recalls is a dead end. Being responsive to problems isn't enough—prevention is the key.

They forged consensus on the need for clear, consistent standards for prevention and a level playing field, and on the need to make adoption of modern, science-based preventive controls – which are a food industry invention and already implemented by many in industry – the norm across the industry.

They also reached consensus on the need to step up import oversight based on the principle of prevention and clear importer accountability for ensuring that food coming into this countries from overseas meets U.S. food safety standards.

Principles in FSMA

This industry-consumer consensus and coalition that achieved passage will be crucial to implementation, and we are committed to working closely with all of these constituencies and being faithful to the goals and principles embedded in FSMA.

In addition to the basic principle of science-based prevention, we are pursuing risk-based approaches to setting standards and deploying our resources so that government and industry can focus on doing those things that make a difference for food safety.

Another guiding principle is the need to understand and respect the incredible diversity of operators across the food system – large and small, widely differing commodities and hazards, and different production and processing systems. We know from working with the produce industry and food processors that, when it comes to preventive controls, one size does not fit all, and that principle will guide us throughout implementation of our new law.

Finally, the only way we will achieve our public health goals is by working in partnership with others. This includes industry, which has prime responsibility for food safety and has expertise on best practices. We also are charged by Congress with working with other federal agencies and state agencies. Our goal is an integrated national food safety system. We also will work closely with foreign governments and international organizations—for instance, we will be engaging very actively with foreign governments on the import provisions in FSMA.

Implementation

Let me turn to how we are proceeding with implementation. With about 50 regulations, guidance documents, and reports and studies needed to implement the FSMA, we have our work cut out for us. We have a duty to fully implement the law and must be systematic so that we get to the finish line in as timely a fashion as possible.

We are using a matrix management system that combines FDA staff from across the regulatory, policy and scientific areas into teams. This takes production out of the usual organizational structure. It allows problems to be raised early and resolved quickly. The teams have a clear charge, have specific deliverables, are empowered to make decisions, and are working through a streamlined clearance process.

We have six implementation teams:

- Prevention standards
- Inspection and compliance
- Imports
- Federal/state integration
- Fees, and
- Reports and studies

The teams are overseen by an Implementation Executive Committee, chaired by me and that includes Mike Landa, Acting Director, Center for Food Safety and Applied Nutrition; Bernadette Dunham, Director, Center for Veterinary Medicine; Steve Solomon, Deputy Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs; Ralph Tyler, FDA Chief Counsel, and David Dorsey, Deputy Commissioner for Policy, Planning and Budget. Our primary job is to make sure the teams have what they need to get their job done.

Prioritization is another important part of our implementation strategy. It is clear that we cannot meet all of the deadlines in the statute. We are focusing first on those with the greatest public health benefit, such as preventive controls, inspection and compliance,

and the import provisions. Even with these priorities, some of the deadlines are difficult. For example, establishing importer accountability is a priority, but we have a new multifaceted import toolkit we need to implement to fully achieve the goal of that provision.

Outreach

As we proceed with implementation, transparency and outreach will be key to success.

We need to help stakeholders understand the new requirements—what FSMA is and what it isn't. We also need to ensure active engagement even before rules are proposed. And we need to help industry prepare for what's coming down the pike.

We have a strategic communications working group in place to ensure outreach and transparency, and a lot of work is going on. We just held a public meeting on imports in March, and we have plans for a public meeting on preventive controls in April and for one on inspection and compliance in May.

We have accepted more than 100 invitations to make various presentations and have completed more than 60 so far. Please remember that the staff doing the work are also the ones called upon to do the outreach, so please bear with us if you have a request for a meeting or a presentation.

We just unveiled a new FSMA web page at www.fda.gov/fsma[1] that includes videos from some of our team leaders, coverage of our import public meeting for those who missed it, numerous questions and answers on FSMA, and a chart of our implementation teams and working groups. It also has a link to a new search engine for recalls that was required by FSMA by April 4—and we met that deadline. The search engine is a good example of how we worked with consumer groups and industry in a collaborative manner.

Closing

In closing, we are well organized to deliver on our statutory mandates in as efficient a manner as possible. We will continue a multitude of outreach activities to be sure you are involved. We need your ideas. We are counting on you. I appreciate the opportunity to update you on our progress and look forward to working with you in the months and years to come.