

The FDA Food Safety Modernization Act: Putting Ideas into Action

Michael R. Taylor
Deputy Commissioner for Foods
Food and Drug Administration

FDLI Food Safety Conference
January 27, 2011

Thank you for that generous introduction and warm welcome.

This moment has been a long time coming – a moment when we're no longer talking about the need for food safety legislation but rather how we're going to implement it.

It is worth remembering how we got here. We got here with hard work, by confronting thorny issues, and most importantly of all, by working together.

Hard work -- if anyone thinks this has been easy, they just need to remember all the National Academy studies calling for these reforms over the past decade and all the work so many put into getting the bill passed.

Confronting thorny issues – the complexity and diversity of our food supply has grown dramatically in the last generation, and, as the new law reflects, the food safety issues we face are just as complex and diverse.

Working together – this law would not have happened without the coalition of industry, consumers, and members of the House and Senate that pushed this legislation over the finish line by staying together and by staying focused on a common vision of how we can reduce the unacceptable costs that foodborne illness imposes on consumers and the food industry.

Thank you, again, for that hard work, that willingness to take on the thorny issues, for working together.

We all hailed the FDA Food Safety Modernization Act as historic when Congress passed it and President Obama signed it.

In fact, some may well think its official name is "The Historic Food Safety Modernization Act."

But what makes this new law so historic? – other than the fact that it had been more than 70 years since our nation's food safety regime was overhauled top to bottom?

First, just consider the profound changes called for in the new law:

- Prevention of foodborne illness, not reaction to problems, is now the guiding principle of our food safety law – with the primary responsibility for prevention resting squarely on the shoulders of food producers and processors.

- For the first time ever, FDA has an inspection mandate and new legal powers to ensure companies are meeting their prevention duty and to stop potentially unsafe food from entering commerce, not just remove it after the fact.
- Congress has made efficient, risk-based use of resources and partnership among government food safety agencies the law of the land.
- And with the law's new importer accountability requirements, there will be added assurances that food from abroad is as safe as domestic food.

All told, Congress has called in effect for a new food safety system – one which meets the public's high expectation that all of us with responsibility for food safety do everything we reasonably can to prevent food safety problems. And that's historic.

But let me suggest that what will truly make the FDA Food Safety Modernization Act historic is what many people and institutions do, building on past efforts, to implement the law and build the new system.

History will be made when prevention is the industry norm, not just the best practice.

Yes, the industry will need the guidance documents and rules from the FDA to know what it means to be in compliance. But many in industry – big and small – have already been pioneers in prevention.

So, even today, food producers and processors can be analyzing their facilities to see where potential hazards may occur, establish the preventive controls to address those hazards, monitor their performance and fix problems when they occur, and document what they are doing.

History will be made when FDA changes its approach to inspection to take full advantage of the preventive controls framework and enhance our public health focus. This means conducting more inspections with our own field force and in collaboration with our state partners, but it also means conducting inspections that better target the key elements of a company's food safety plan and are effective and efficient in determining whether the company is meeting its prevention duty.

History of a kind will be made when we issue our first mandatory recall order. It is important that we have this new power, and we thank the consumer community and the food industry for supporting it. But, let's be clear, a mandatory recall is a sign of failure. It means preventive controls were either not in place or not used effectively. It means a company has not accepted the responsibility for its actions. We don't expect to have many mandatory recalls, but the fewer we have, the more successful we have been.

And history will be made when we bring our system of import oversight into the 21st century. Industry accountability for prevention is not a new idea – we have it for seafood, juice, eggs, meat and poultry – but importer accountability is new. It will take creativity and collaboration to bring this idea to life, but, when we do, consumers can have renewed confidence in all the food on their plates, and the food industry can operate on a level playing field that will only strengthen the global food system.

Finally and most importantly, history will be made when fewer people get sick and we have fewer large outbreaks of foodborne illness. We know the food system is too complex and too dependent on fallible human beings to think we can eliminate all risk. That's impossible.

But we also know that the status quo is unacceptable. We have too much preventable foodborne illness, including 3,000 deaths and over 100,000 hospitalizations annually, many of which result in permanent disability.

We have too many outbreaks that not only make many people sick but also disrupt major sectors of our food system, erode public confidence in the food supply, and inflict great economic harm.

We all know – Congress knows – we can do better. And that's what implementation of the FDA Food Safety Modernization Act is all about.

So the most important history will be made when we change the status quo and measurably reduce the burden of foodborne illness on our consumers and on our food system.

A big task lies ahead. People have been coming up to me and saying, almost sympathetically, "You guys have a big job on your hands!" Well we do, and, while implementation of the new law rests as much with the food industry as it does with FDA, it's critical we do our job well.

So, let me give you a sense of what you can expect from FDA.

First, we'll hit the ground running. We have a strong team of experts with experience in preventive controls from both an industry and regulatory perspective, and we have already done a lot of work in anticipation of the new law.

We've been working hard for the last year on produce safety standards, a preventive controls rule, and new domestic inspection and import strategies. So we embark on implementation with considerable momentum.

Second, the vast workload that comes with the new law – over 50 new regulations, guidances, programs and reports to Congress – means we have to set priorities for our work. We will focus on and prioritize the key building blocks for prevention.

Thus, you can expect timely completion of the rulemakings required to set standards for produce safety, preventive controls, and intentional adulteration.

You can expect that we will be ready to use our new administrative enforcement tools within the timeframes prescribed by Congress.

And you can count on us giving high priority to building the new import oversight system.

Third, we are absolutely committed to full, transparent engagement with all stakeholders – industry, consumers, public health experts, and other government colleagues – to take advantage of their expertise and diverse perspectives. We will be reaching out in multiple ways, including regular meetings and stakeholder calls, on-line updates on the status of implementation, and substantive dialogue on key issues.

Finally, you can count on FDA to maintain its strong commitment to public health and to achieving the new law's public health goal in a manner that is in keeping with the consensus that gave rise to the legislation.

We see food safety as a widely shared goal and everybody's responsibility. We embrace our role in marshalling the best science and judgment to guide how that responsibility can be met.

We know we'll make food safer by working collaboratively within government and across public-private lines – it can't be us versus them.

And, in a world of finite resources, we'll change how we work to make the best use of every resource we have.

Make no mistake, resources will be a continuing issue as we work to build the new food safety system. As I hope I've made clear there is a lot FDA can and will do to put the new law into action and build the foundation for a new system, but completing the system – fulfilling the Congressional vision embedded in the new law – will require new resources and investment. We look forward to working on this issue with our colleagues in industry and the consumer community, and with leaders in Congress.

And so, let me close by reminding you what got us here.

Hard work.

Confronting thorny issues.

Working together.

These same attributes will be just as essential if we're to succeed in implementation.

We are realistic about the challenges we face. We know we can't take success for granted. But if we all commit ourselves to implementation in the same way we did to get the law passed, we will succeed.

On behalf of Commissioner Hamburg and all of us at FDA, I can assure you of FDA's commitment to successful implementation.

It is also the commitment of the President who established the President's Food Safety Working Group. It is the commitment of the Secretary and top leadership of HHS. It is the commitment of our partners at the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the other federal food safety agencies and our colleagues at the state and local levels.

And we will count on you.

We have history to make. All of us. Together.

Thank you.