

FDA FOOD SAFETY MODERNIZATION ACT

“Prevention and Food Safety: Two Lenses, Common Vision”

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(remarks as prepared)

Opening

It's a great pleasure to be back at George Washington University. I fondly remember my days here as a research professor in the School of Public Health and Health Services just before returning to FDA in 2009. Dean Goldman is a long-time friend and colleague, and I appreciate the hospitality she and the School have demonstrated in hosting this event.

But, as much as I enjoyed my time in academia, it is a great privilege for me to be back at FDA working with my many wonderful colleagues there at a time of great challenge and great opportunity to make needed change in our nation's food safety system.

The legal and policy framework for the change we are pursuing is provided by the new – we often say “historic” – FDA Food Safety Modernization Act (FSMA), which President Obama signed into law on January 4, 2011. This new law is historic in part because it overhauls for the first time in more than 70 years the basic statutory tool kit on which we have been relying to tackle foodborne illness.

The Food Safety Modernization Act is historic also because it establishes in law a new public health paradigm for FDA's food safety program. The new law shifts our food safety focus from reaction and response to prevention of the problems that can make people sick -- from catching food safety problems after the fact to systematically building in prudent preventive measures across the food system, from the farm to the table.

It does this by creating a comprehensive regulatory framework for prevention; strengthening FDA's inspection, compliance and outbreak response

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tools; modernizing oversight of food imports; and calling for enhanced partnerships as part of a more integrated food safety system.

But, as important as anything else, FSMA is historic for the broad coalition of consumer and industry groups that made its enactment possible and for the common vision the law embodies for a modern food safety system – one that serves consumers and industry alike and that can support a vibrant, diverse food system working at both local and global levels to feed our population.

I want to talk today about that common vision and the prevention principles in which it is grounded. Whether we look at today's food safety challenges through the public health lens or through the lens of what it takes for the food industry to meet the high expectations of American consumers, we see the same basic principles.

This common vision and the prevention principles on which it is based are important not only because they served to get the law passed, but also because they must – and they will – sustain the years of effort that lie ahead to implement the law.

To be sure, within our common food safety vision lie many challenging issues and ample room for debate and legitimate differences as we go down the implementation pathway. But we at FDA have confidence in the vision that guides us. We are committed to it. And we look forward to working with all of our food safety stakeholders to fulfill it.

Prevention as a Common Vision

At the highest level, the prevention vision embodied in FSMA is simple: we will make food safer by setting and gaining high rates of compliance with standards that set the bar for industry efforts to prevent hazards from entering the food supply. FSMA provides FDA with a strong mandate to set such standards, as well as important new inspection and enforcement tools to achieve compliance.

But the prevention vision goes deeper than this new regulatory tool kit. It is grounded in principles and approaches that the public health community has applied to a range of health problems over the years and that the food industry pioneered and is already applying in many instances to ensure food safety.

Prevention, of course, is not a new idea in public health – indeed, it is a foundational principle. Historical examples abound – immunizations for childhood diseases, fluoridation of the water supply for dental health, and food

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fortification for nutritional deficiencies. And today, we are working to foster healthier diets and more exercise to help prevent heart disease, diabetes and other chronic disease.

In hindsight, many such interventions may seem obvious, but we know that prevention works best in public health when we take a systematic, knowledge-based approach.

- First, we must recognize that a problem exists.
- Second, we must understand as much as we can about its causes.
- Third, we must devise the appropriate preventive measures and implement them.
- And last, we must monitor the effectiveness of our interventions and adjust as needed.

This is just good public health practice.

It is also the approach to food safety that the food industry pioneered in the early 1960's, originally to guarantee as much as possible the safety of food for space flights. Needless to say, reacting to food safety problems while orbiting the Earth is not a good strategy, so food industry experts developed a system known as Hazard Analysis and Critical Control Point Systems – HACCP – to build prevention into the processing of the food.

HACCP is very much in line with good public health practice. It focuses systematically on:

- understanding the specific food safety hazards that could affect a particular food production operation,
- devising and implementing scientifically validated controls to minimize the hazards,
- monitoring the implementation of preventive controls to verify effectiveness, and
- making corrections and adjustments as needed, based on experience.

Many food processors implement HACCP today as part of their own food safety and quality assurance systems, and, with industry support, HACCP approaches have been implemented by FDA and USDA as a regulatory standard for low-acid canned food, seafood, juice, meat and poultry. HACCP is also an internationally recognized framework for food safety, through its adoption by the United Nations Codex Alimentarius Commission and other national governments. HACCP-based prevention is thus already recognized as the operating principle and standard for food safety by much of the food industry.

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Despite their commonalities, the public health community and the food industry no doubt look at prevention to some extent through different lenses. The public health community and consumers are focused, of course, on reducing the frequency and public health burden of foodborne illness. Consumers also want to have confidence in the food they buy and serve their families, and, from a public health perspective, we don't want doubts about food safety to deter consumers from choosing foods that are important to a healthy diet, like seafood and fresh produce.

We know the best way to both reduce the risk of illness and maintain strong public confidence is to have in place credible and effective systems for preventing the contamination incidents and outbreaks that jeopardize both goals.

Members of the food industry also have strong interests – personal and professional – in preventing foodborne illness. At a personal level, people in the food business certainly don't want to harm their customers or to produce food they wouldn't happily serve to their own families. From a strictly business perspective, however, the food industry also has a strong interest in avoiding the direct costs, market disruptions, and loss of consumer confidence that follow contamination incidents and illness outbreaks.

We've seen the impact significant incidents can have, ranging from *E. coli* O157 in spinach and melamine in pet food, infant formula and milk-based products, to *Salmonella* typhimurium in peanut products and *Salmonella* Enteritidis in shell eggs. These incidents add to the industry's impetus for implementation of HACCP or similar systems of preventive controls for food safety by food producers and for inclusion of preventive controls in purchase specifications by retailers and other food supply chain managers. They know systematic prevention is a key to business success.

So, while the consumer and public health communities and the food industry may be looking at food safety through somewhat different lenses, they are embracing a common vision. Prevention of food safety problems is in everyone's interest. That shared understanding and the vision that goes with it is why FSMA was enacted.

Implementing FSMA: The Road to Prevention

Embracing the common vision of prevention and enacting FSMA are critical steps on the road to prevention, but they are just the first steps. Fulfilling the vision and successfully implementing the new law are an even greater challenge, due to the inherent complexity of the food system and the complexity of the food safety problem.

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From a public health perspective, there is no doubt we have a problem. The most recent analysis by the Centers for Disease Control and Prevention of the epidemiological evidence shows that about 1 in 6 people in the United States get sick each year – that’s a total of 48 million people. Of that number, about 128,000 are hospitalized, and 3,000 die. Foodborne illness places a special burden on immune-compromised individuals, a growing segment of our population, and we know that foodborne illness can be much more than a transitory gastrointestinal illness. It can cause life-long, chronic disease and disability, including arthritis and kidney failure.

That’s why, for public health reasons alone, we need to focus so strongly on prevention, but the first thing to be clear about is that there are no magic bullet solutions to today’s food safety problems. Thus, at both the food system and individual firm levels, we need to apply the same systematic step-wise approach to prevention that has been used for other public health problems. We must understand as much as we can about the problem and its causes, devise the appropriate, science-based preventive controls for particular hazards and food production settings, monitor their effectiveness, and adjust the controls as needed based on experience. Broadly speaking, that’s what FSMA commands that we do.

It sounds simple, but make no mistake, the complexity of the food system makes implementing FSMA’s command a great challenge. That’s not an excuse; it’s a reality. Our far-flung global food system involves literally millions of commercial actors engaged in producing, processing, transporting, storing and marketing food. Hazards can enter the food supply at any point along highly extended supply chains. Likewise opportunities to minimize hazards exist throughout the system.

From both a public policy and private sector food safety management perspective, we must embrace this complexity and take a systems approach that addresses the food safety challenge from farm to table. And we must recognize that all of us – industry, government, and consumers as well – have a role in preventing foodborne illness.

To compound the challenge, we know that the food supply is constantly changing. The volume of imported food has more than doubled in the last decade. New products and new methods of food preparation are introduced all the time, offering consumer benefits but sometimes raising new food safety management challenges. And, in the dynamic world of microbiology, the pathogens themselves evolve and new hazards emerge, such as E. coli O157:H7 and the class of shiga-toxin producing E. coli.

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In many ways, we're still connecting the dots when it comes to knowing the causes of contamination in the food supply and designing prevention systems. And this will likely be an ongoing process. That is an important part of our challenge. We must design a public health prevention program that is based on what we know now, with the understanding that it must adapt to new information about hazards in the food supply and what works to minimize them.

In the context of today's complex and dynamic food system, the FDA Food Safety Modernization Act provides a sound framework for implementing our prevention vision.

- FSMA is **comprehensive** in its recognition that prevention should be pursued to minimize hazards at each step on the farm-to-table spectrum and with respect to all commodities and processing settings in which hazards arise and can be minimized.
- FSMA is **risk-based** in the sense that it calls on both FDA and food firms to target their prevention efforts based on a scientifically grounded understanding of what measures will make a practical difference for food safety.
- FSMA is **flexible** in that it recognizes that prevention standards and preventive control systems properly differ depending on the setting – such as farm, processing facility, or transport – and the nature of the commodity and hazards being addressed.
- FSMA is **adaptable** in that, at the firm and system level, Congress expects us to learn from experience and from new science and make changes accordingly over time.
- FSMA recognizes food safety is a **global** concern by strengthening FDA's mandate and tools to apply the same prevention standards to imports as we will apply to domestically produced food.

I can illustrate these points with a few examples of how FDA envisions implementing FSMA.

Preventive Controls from Farm to Table

The FSMA mandate to establish science-based, minimum standards for safely producing and harvesting fruits and vegetables on the farm provides a good example of the complexities involved in developing preventive controls and also the need for flexibility. Produce safety is one of our most technically

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challenging food safety tasks due to the diversity of crops, regions, growing and packing practices, and size of operations.

Fortunately, FDA began working on preventive controls for produce before FSMA was enacted, so we had a head start. We've invested much effort to get as much input from the produce community as possible before starting to write any regulations. We've held listening sessions in 13 states and visited farms of all sizes. We're also worked with experts in the industry and at other federal agencies, such as the U.S. Department of Agriculture. This outreach put us in a good position to develop prevention standards that are not only effective but practical for the diversity represented by the industry.

We are well on our way to developing a proposed produce safety rule that addresses areas such as employee hygiene, water quality, soil amendments, and animals in the growing area, as FSMA mandates.

In food facilities, such as processing and packaging plants, we will be proposing rules that are grounded in the widely embraced principles of preventive process control for food safety, similar to HACCP. The law requires each facility to take a number of distinct steps to ensure safe food production. Each facility has to: (1) evaluate the hazards that could affect food safety, (2) specify what preventive steps, or controls, to put in place to minimize or prevent these hazards, (3) specify how the facility will monitor these controls to ensure they are working, (4) maintain routine records of monitoring, and (5) specify what actions the facility will take to correct problems that arise.

For example, in a facility that produces peanut butter, factors such as ingredient safety, sanitation, and cross contamination would have to be considered. After the outbreak of *Salmonella typhimurium* in peanut butter in 2008 and 2009, which caused 714 cases of illness, the company had to re-evaluate the hazards in its facilities so this wouldn't happen again. Such review and correction – and a sharp focus on specific hazards – will become the norm under a system of preventive controls.

The new norm embodied in HACCP and similar approaches to preventive controls has already transformed the way many food companies approach food safety. They are looking at the system as a whole, including the safety of their raw materials, how manufacturing processes and controls are working to minimize scientifically identified hazards, and how flaws or failures can be detected and promptly corrected. And many companies are building new cultures of food safety in which all employees understand their role and are well trained to perform it.

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This transformation in the industry is also transformative for FDA's role. Historically, FDA's inspectors have inspected food processing facilities for basic sanitation and to detect visible problems with the facility or the product being produced. Under FSMA's new norm, FDA inspectors will still be looking for what's gone wrong, but they will also be looking to verify that firms are implementing the systems needed to do things right.

This is a transformative shift in FDA's role. It respects industry's primary responsibility for producing safe food. It makes much better use of FDA's resources. And it provides a much better assurance to consumers that effective measures are being taken to prevent problems on a continuing basis, not just when the inspector is in the facility.

Beyond processing facilities, FSMA also directs FDA to set prevention-oriented standards to protect food safety while food is in transport, after it has left a farm or processing facility. This is another area where preventive controls have to adapt to the situation. Controls at this stage of the farm-to-table chain would not likely involve complex systems but rather practical steps that would prevent contamination, such as cleaning trucks between shipments and keeping refrigerated trucks at the correct temperature.

So far, I have focused on the sections of the farm-to-table chain that FSMA directly addresses. But a food supply chain is only as strong as its weakest link, so we can't ignore the importance of preventive measures at retail establishments and in the home—the end of the farm-to-table chain.

At retail, we work closely with state, local and tribal agencies, which have the primary responsibility to regulate restaurants and other establishments. FDA assists by producing the Food Code, which contains science-based, prevention-oriented food safety principles, to serve as a model for state, local and tribal agencies to develop their own food safety rules.

In homes, we have the final opportunity for prevention in the context of a systematic, farm-to-table approach. This is not about blaming consumers for foodborne illness. Under FSMA, the primary responsibility for ensuring food safety rests with the farmer, processor and transporter, but consumers also play a role by following good food safety practices at home. Food safety is a widely shared responsibility.

FDA supports consumers in playing their role through a broadly collaborative approach to consumer education. FDA works closely with USDA and CDC, and through the Partnership for Food Safety Education – a coalition of

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government, industry and consumer stakeholders – to develop science-based consumer messages and disseminate them as a means of changing behavior.

FDA initiatives at the retail and consumer levels are not part of the FSMA mandate, but they are very important to the integrity of the farm-to-table food safety chain and the effectiveness of our prevention strategy.

When Prevention Fails

With implementation of FSMA, we expect great progress in preventing foodborne illness. We know, however, that in our complex global food system run by millions of fallible human beings, perfection is impossible. We will continue to have outbreaks, and responding to outbreaks will continue to be an important function for FDA and our partners at CDC and in state and local public health agencies.

We see outbreak response as an integral part of the prevention system. Rapid identification and containment contributes to prevention by reducing the number of people who get sick. But we also have to see outbreaks as a learning opportunity that can help inform future prevention efforts.

This means working with our partners to conduct multi-disciplinary follow-up investigations to get to the root cause of an outbreak and disseminating that information to support the design of better prevention systems. This is part of good public health practice. It is also in keeping with the practices of food safety leaders in the food industry, who know that learning from experience and adapting based on new knowledge is a key element of effective, prevention-oriented food safety management.

FDA is in the process of strengthening our response capabilities by creating a dedicated staff that will be led by a new chief medical officer responsible for overseeing all aspects of how FDA prepares for, responds to and learns from foodborne outbreaks.

Conclusion: A New Food Safety System

FSMA builds on a long history and strong foundation of food safety efforts at FDA. But is also marks an historic transition from a statutory framework designed primarily for reaction to one that embraces prevention as the central principle. FSMA calls on FDA to lead the construction of what really amounts to a new food safety system, based on the public health principle of prevention and suitable for today's global food system and the high expectations of America's consumers.

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FDA enthusiastically welcomes this challenge. The new system will not come easily, and it will not come overnight. And it will take investment – investment in science to better understand hazards and effective interventions, training of FDA staff, information sharing systems, state and local food safety capacity, and the implementation of a dramatically new paradigm for import oversight.

We know, however, that these investments in prevention can produce a food safety system that is more effective and efficient for government and industry alike, and a system that consumers can trust is doing everything reasonably possible to make food safe.

Building this new system will require hard work not only at FDA but by people throughout the food system. I think we're all up for it, and we welcome all of you into the process.

We will continue our outreach to the community both before and after we publish proposed rules, and you can follow our progress and get more information about our implementation of FSMA on our website at fda.gov/fsma. We need your ideas and input, so let us hear from you. Thank you.