

The FDA Food Safety Modernization Act: A New Paradigm for Importers

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Good afternoon, and thank you, for that generous introduction. I am very pleased to be here.

It is particularly important and timely for me to participate in this important Global Foods Forum, as we in the United States are just embarking on the implementation of sweeping food safety reform legislation.

But, I have to say...

“Carrying coals to Newcastle” was the phrase that came to mind as I thought about speaking to you today about the passage of the Food Safety Modernization Act and its potential impact on topics such as:

- our globalized food system,
- the critical importance of integrating food safety into supply chain management, and
- the vital role in food safety that accredited third-party auditors and certifiers can and will play.

Just reciting those topics sounds to me like a brief summary of the annual agendas of the Global Food Safety Initiative over the past nine years.

My goal today is to add a U.S. perspective to the mix, in light of our new food safety law, which Congress just passed at the end of last year and President Obama signed on January 4th.

And I want to convey today one message loud and clear:

The FDA Food Safety Modernization Act only heightens the imperative that we in the United States work in partnership with the global food safety community to meet the public’s high expectations for the safety of food, no matter its origin.

But first, let me acknowledge and express my appreciation for the robust and vital dialogue the GFSI has established on how to make assurance of safety an integral part of the global food system.

And here, I'm "preaching to the choir," if you'll indulge another metaphor.

By bringing together retailers, manufacturers, auditors, and others with a stake in the global food industry...

You have made it clear that food safety is not only the right thing to do, it is good business.

Let's focus for a moment on both sides of that coin.

First, the right thing to do....

Consumers around the globe expect and demand food safety.

And, of course, helping to ensure food safety is a core public health mission of the Food and Drug Administration.

It's also a continuing, dynamic challenge.

Our Centers for Disease Control and Prevention recently released its latest and best estimate of the burden of foodborne illness in the United States.

Each year, 1 in 6 Americans can expect to experience foodborne illness. Of that number, more than 120,000 will be hospitalized, and, tragically, 3,000 will die.

We know we can do better. Most of those illnesses are preventable. We know we must do better. It's the right thing to do.

Good business.....

All of you in this room acutely understand the major disruptions to our economies and to international trade that occur in the wake of major foodborne illness outbreaks and product recalls.

You understand how these crises can undermine consumer confidence for months and years to come.

Again, we know we can do better, and we must do better.

That understanding, shared by industry and consumers alike in the United States, brought together an unprecedented coalition to gain passage of our new law.

And that understanding underlies the consensus we have in the United States that science- and risk-based prevention of food safety problems is good for consumers and good for the food industry.

We also know that the food safety challenge and food safety solutions have to be understood and addressed globally, which is why our new food safety law establishes a new paradigm for FDA's oversight of imported food.

In fact, the globalization of the food supply was a major force driving passage of the Food Safety Modernization Act.

Consider just a few numbers: 15 percent of the entire U.S. food supply is imported, including about 50 percent of our fresh fruits, 20 percent of our vegetables, and 80 percent of our seafood.

The U.S. situation is not unique by any means.

For those of you who live and work in the European Union countries, imported food is a fact of daily life.

And many emerging economies recognize that food exports can help drive their economic growth.

It is for these reasons – high public expectations and expanding trade in food – that the effort to improve food safety and to build prevention in from farm to table is a global movement...and is good business.

It is a global movement that, very importantly, recognizes that the primary responsibility for prevention rests with business – with those who produce, process, import, and market food.

Consumers certainly have a role to play as food handlers and preparers.

And, of course, government plays a vital role in providing scientific leadership, setting standards for effective prevention of food safety problems, and ensuring through inspection and other means that those standards are understood and met.

But everything we do to improve food safety rests on the foundation of the food industry fulfilling its duty to do everything it reasonably can to make food safe.

And THAT is why the work of GFSI members has been and will continue to be so important in helping the food industry fulfill its responsibility for food safety.

GFSI has championed the crucial proposition that food safety must be integrated from the beginning into any food business and woven throughout the fabric of supply chain management.

We at FDA applaud GFSI for that.

Today, I want to assure you that respect for the food industry's foundational role in food safety, recognition of the complexity of the global food supply, and the idea of supply chain management will inform all we do in implementing our new food safety law, and that includes its import provisions.

So, let me devote the rest of my time to a brief overview of the FDA Food Safety Modernization Act and its implications for food imported into the United States.

I want to let you know what you can expect of FDA in the near future as we work to implement the new regulatory provisions of the law... and over the coming years as those provisions take root.

As I'm sure you know, FDA's jurisdiction and the new law cover about 80 percent of the U.S. food supply, essentially everything but meat and poultry, and nearly all imported food.

The core mandate of the new law is for FDA to set standards for risk-based preventive controls for all the foods we oversee – regardless of type and whether produced domestically or overseas.

FDA also has new tools for ensuring high rates of compliance with those standards. These include for the first time an inspection frequency mandate – at both domestic and foreign food facilities, expanded records access authority, and new administrative enforcement powers.

The key, however, is that the new law explicitly places primary responsibility for food safety – for prevention – on food producers and processors.

Think of it as supply chain management written into law.

And, as I said, Congress made very clear that this responsibility does not stop at the water's edge.

Both domestic and foreign producers and processors must meet their new responsibilities to ensure the safety of food sold in the United States.

Importers will, for the first time, have a clearly defined responsibility and accountability for the safety of the food they bring into our country.

The new importer accountability provisions require importers to implement a foreign supplier verification program.

They will need to provide adequate assurance that imported foods have been produced under appropriate risk-based preventive controls that provide the same level of public health protection as those required of our domestic food industry.

This clarification and strengthening of the importer's responsibility for food safety is the centerpiece of the new law's import safety reform, but it is not the only thing.

As I mentioned, Congress has directed FDA to do more inspections in foreign countries to ensure compliance with U.S. standards.

But Congress also recognized that building capacity for food safety in other countries and partnering with them are smart ways to leverage our resources and do more to prevent problems from occurring.

So, the new law charges us with helping to build capacity for food safety in other countries that export to the United States and working more closely with foreign governments on food safety.

Leveraging resources and preventing problems are also the guiding principles for an element of the new law that is no doubt of great interest to many of you here today. Namely, accredited third-party certification – which we see playing a crucial role in providing the assurances we all seek about the safety of globally-traded food.

Under the new law, we are charged with establishing a system for accrediting third-party auditors of foreign food facilities – auditors who can certify a firm's or a facility's compliance with U.S. standards with rigor, objectivity and transparency...and on whom FDA can rely as part of the food safety assurance system.

That is a tall order, but we intend to meet it.

And we think we can, because we began thinking about and working on this issue long before the law was passed.

The voluntary third-party certification guidance that we issued in January 2009 gives us a solid foundation for moving forward, and should give you a sense of how we have approached recognition, or indirect accreditation, to date.

Will we be open to new ideas and new approaches?

Absolutely! The primary purpose of my trip to Europe is to learn and listen.

We know that continued conversations with all of our stakeholders in this area will lead us to the best result, which is where we want and need to get.

And there will be plenty of issues, since the new law envisions multiple roles for third-party certification.

The first is to help importers meet their new responsibility to verify that the food they import into the United States is in compliance with U.S. standards. Some importing firms have integrated robust food safety verification procedures into their supply chain

management systems and will likely be able to fulfill their verification responsibility on their own.

Others have not and may want to rely in whole or in part on the certifications of third-party auditors.

In either case, the critical issue is ensuring importers have the means to verify that their suppliers have systems in place to produce safe food.

Second, importers participating in the new law's voluntary program for expediting the importation of food into the U.S. must accompany their food shipments with safety certifications. We expect that many companies will seek to participate in this program, and we must have an accredited third-party certification program in place to meet that demand.

Finally, FDA can require an accredited third-party certification as a prerequisite for the importation of high-risk foods into the U.S., and we will be prepared to do this when we believe it necessary to protect the health of our consumers.

So, you can see that we envision accredited third-party certification playing a vital role in our future food safety system.

It is a way of drawing on the efforts of private actors in the system to provide assurances on which the public and FDA can rely.

It is based on a model of collaboration and partnership to improve food safety, involving food producers and processors, private auditors, and private accrediting bodies.

And it is a way to ensure that the certifications on which we rely are rigorous, objective, and transparent.

So, we at FDA know we have a big job ahead of us to implement our new food safety law.

We know we will be measured in the near future by how quickly and how well we do the job.

And we know that, to do the job well, we will have to set priorities.

We will place a high priority on implementing the import provisions of the law and the produce safety and preventive controls provisions with which they intersect, as well as other of the basic building blocks of prevention.

We will also place high priority on engaging at every step our wide array of stakeholders, including members of the import and export community.

We need your expertise and experience, and we will need your support to bring this new law to life as a practical, effective tool for improving food safety.

You could say our goal is both straightforward and herculean:

A prevention-oriented, risk-based food safety system that protects our consumers from avoidable harm while preserving their access to the wide array of food choices made possible by today's global food marketplace.

If we can do that, you may be thinking, maybe we can also do something about the weather.

But, let me close by repeating what I said at the outset: Consumers around the world, not just in the United States, expect and demand safe food, no matter its source.

We need to live up to those expectations.

With the kind of collaboration and dialogue fostered by GFSI and with our collective commitment to building a 21st century food safety system suitable for a global food system, I know we can and we will.

Thank you.