THE ESSENTIAL GUIDE TO THE FOOD SAFETY MODERNIZATION ACT

Everything You Need to Know about America’s Coming Food Safety Revolution

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Contents

The Evolution of American Food Safety ................................................................. 4
  Why Food Safety Modernization? ................................................................. 5
  What Does FSMA Mean for Business? ......................................................... 6
When will it Actually be Implemented? ............................................................ 7
  Three Reasons we Know FSMA is Happening ........................................... 8
Where is it at Right Now? ................................................................................. 8
  Landmark FSMA Rules Published .............................................................. 8
The Rules ........................................................................................................... 9
  What’s in Effect Now? .................................................................................... 9
    Mandatory Recall Power ........................................................................... 9
    Record Submission ..................................................................................... 9
    Whistleblower Protection ......................................................................... 9
    Increased, Risk-Based Inspections ........................................................... 9
    Suspension of Registration ....................................................................... 10
First FSMA Rules ............................................................................................. 10
  Order on Detention of Food ................................................................------- 10
  Rule on Imported Food ................................................................................. 10
  Other ............................................................................................................. 10
What’s Coming? ............................................................................................... 11
  Preventive Controls for Food Facilities ....................................................... 11
  Science-Based Produce Safety Standards ................................................ 11
  Foreign Supplier Verification Program ...................................................... 12
  Accredited Third-Party Certification .......................................................... 12
What Else? ....................................................................................................... 12
Meeting Tomorrow’s FSMA Requirements Today .......................................... 13
  FSMA vs. SQF and HACCP ....................................................................... 13
  HACCP Central to Rules ............................................................................. 14
  FSMA’s Four Pillars .................................................................................... 14
    Preventive Controls .................................................................................. 14
    Inspection and Compliance .................................................................... 15
    Imported Food Safety .............................................................................. 16
    Response ................................................................................................... 17
The Role of Technology in Compliance .......................................................... 18
Be Prepared ...................................................................................................... 20
  About Intelex ............................................................................................... 21
Endnotes ........................................................................................................... 22
The Evolution of American Food Safety

The landscape of American food safety is dramatically changing. While the pace of this change may not seem as immediate as some expected when the sweeping Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, some of the Act’s provisions have already been implemented and others are poised to take effect in the coming months and years. Though it is only being gradually realized, the net effect of the Act’s implementation will fundamentally reshape the climate of food safety in America and around the world. It will also radically change how most food and beverage companies do business.

The Act can appear daunting in scope, and many businesses are scrambling to figure out what is expected of them, what can be done to prepare for the Act’s as-yet-undefined requirements, and how the potential costs associated with the new law can be minimized. Fortunately, while the Act appears complex at first blush, on closer inspection its elements are quite simple. Businesses have been provided with a number of clues that provide a sense of how FSMA’s core provisions will materialize as in-progress and incoming rulemakings are defined and finalized. It’s also becoming clear that the tools that will help affected businesses meet FSMA requirements are already available and can be leveraged today to ensure compliance tomorrow.

In this ebook we’ll take a look at:

- Why FSMA was legislated.
- When it is actually going to be implemented and enforced.
- What it means to businesses in the U.S. and suppliers around the globe.
- What FDA powers and requirements are currently in effect and what is incoming.
- What the Act’s key provisions will look like when they are fully implemented.

Whether you’re new to the Act, looking for a refresher, or simply want an outlook on what FSMA requirements are coming down the pipes, you’ll find this ebook a useful resource for understanding FSMA and what it means to the food and beverage industry.
**Why Food Safety Modernization?**

At its heart, FSMA signals a paradigm shift from an archaic model of reactive food safety management to a risk- and hazard-averse model of proactive management. Dialogue surrounding FSMA can become bureaucratic and convoluted at times, and as a result it can be hard to remember the simple reason it came about in the first place: that American families are entitled to a safe food supply, regardless of where it comes from. The American people need to know that government, regulators, and the food and beverage industry have all done their utmost to ensure a citizen’s health, will not be negatively impacted by the food products they and their children consume every day.

Prior to passage of FSMA in late 2010 and President Barack Obama signing it into law in 2011, American food safety rules had not been updated in nearly 75 years, since Franklin D. Roosevelt passed America’s first food safety legislation in 1938. Public outbreaks of foodborne illnesses and resultant product recalls have always been a reality and every year, nearly 50 million U.S. citizens get sick from foodborne illnesses, with about 128,000 hospitalizations and 3,000 deaths. However, in recent years such events have been trending upwards. Between recent highly publicized outbreaks and recalls associated with foods as diverse as egg products, cantaloupe, ground beef, and cookie dough, one doesn’t have to look very far for a large-scale instance of compromised food safety. According to a recent Center for Disease Control (CDC) report of 39 outbreaks and 2,348 illnesses recorded between 2005 and 2010, nearly half occurred in 2009 to 2010.

This trend can be at least partially attributed to an increasingly globalized food supply chain. Over 15 per cent of food consumed in the U.S. is imported, a statistic that rises when looking at specific commodities, such as seafood, fresh fruit, and spices. Existing food safety regulations, having been crafted in the 1930s, insufficiently provided adequate food safety in the face of this economic reality.

On top of this, food safety confidence in America is declining. According to a recent Center for Food Integrity poll of over 2,000 Americans, confidence in the capacity of government to ensure food is safe is eroding. Respondents were asked whether government agencies were doing a good job ensuring citizens consumed safe food, responses fell to 5.40, down from last year’s 5.63. Responses to statements were given on a scale of 0 to 10, ranging from “Strongly Disagree” to “Strongly Agree.”

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1. The FDA’s foreign inspection mandate is approximately 600 facility inspections annually. Under FSMA, that number will double each year for at least 5 years.
With this in mind, in 2010 a bipartisan majority of Congress passed FSMA to better safeguard the U.S. food supply and the law has now been in effect for just over a year. As with any piece of sweeping legislation, the Act has met some criticism from certain quarters: some have complained that it doesn’t go far enough while others feel it unfairly impacts small businesses (a concern largely addressed in the law’s Tester amendment). But whether food and beverage companies support the act or not, it is a legal reality and compliance will be mandatory.

**What Does FSMA Mean for Business?**

At a high level, FSMA represents a paradigm shift from reactive to proactive food safety management. On a slightly more granular level, food companies will have to comply with an array of new requirements that will affect how they do business in a variety of ways.

For example:

- **More inspections:** The FDA will increase the frequency of inspections, especially for high-risk industries.
- **Certification:** When it is fully implemented, food and beverage businesses will have to be FSMA-certified to handle/distribute/manufacture food products – it will simply be a requirement of doing business.
- **Prevention standards and controls:** Businesses will have to implement a prevention-based food management framework and a food safety plan.
- **Fees:** There will be assorted fees, namely associated with inspections.
- **Supplier verification:** Businesses that import foods internationally will have to ensure that their suppliers are verified.

These are only some of the key ways FSMA will impact businesses and while rulemakings associated with some of the requirements have yet to be drafted, others are currently in effect. In the next two parts of this guide we’ll separate these aspects of the Act and take a look at each of the key requirements.
When will it Actually be Implemented?

Before we dive into FSMA, it’s important to acknowledge the significant skepticism surrounding FSMA and the implementation of its various rules. After all, the Act was signed into law nearly two years ago, and while some of its smaller requirements are already enforced, the key planks of the Act have yet to be implemented. Some have proposed that FSMA has come to a full stop and there is little momentum to fully realize the Act, but nothing could be further from the truth.

Three Reasons we Know FSMA is Happening

Besides the fact the Office of Management and Budget is legally required to implement FSMA, we can take a few cues from recent events:

1. The 2012 Election is Over: During the Fall 2012 Presidential election, there was rampant speculation that FSMA rulemakings were being held up by the administration for political reasons amid a voting public that was increasingly polarized over regulations. While there is no direct proof the election played a role, analysts and legal experts widely believe the President’s re-election laid the ground for an expedited implementation of remaining FSMA rulemakings. Indeed, as OMB spokesperson Moira Mack noted in late-November 2012, “The Obama Administration is… working as expeditiously as possible to implement the food safety legislation we fought so hard for. When it comes to rules with this degree of importance and complexity, it is critical that we get it right.” With announcements of two sweeping FSMA rules in January 2013, any lingering doubt FSMA was happening should have been put to rest.

2. The OMB and FDA are Being Sued: In August 2012, amid widespread concern within the food safety community that the OMB and FDA were taking too long to provide proposed rulemakings, The Center for Food Safety filed a suit against both organizations for their failure to implement a number of critical FSMA regulations. The FDA submitted four key draft rules to the OMB over a year ago, but the OMB has yet to provide any proposed rulemakings for public comment. Since the legally binding review limit is 90 days, The Centre for Food Safety is alleging the OMB and FDA are dragging their heels on FSMA implementation. Though both government organizations have attributed the delay to the complexity of FSMA rules (which will require over 1,000 pages) and government lawyers have tried to get the suit dismissed, that’s unlikely as FSMA was clear about FDA’s requirement to put the law into effect by specific deadlines.

3. The First FSMA-Related Facility Suspension has Already Happened: Proving that the already implemented FSMA rules have teeth, in November 2012 the very first facility was suspended under a provision of the Act. Operations at a New Mexico-based food manufacturer were suspended immediately and an extensive product recall was ordered after the FDA notified the
company president simply because the facility was suspected of having Salmonella-contaminated products. In a harshly worded letter, the plant was told it could only resume operations after it determined the company implemented procedures thorough enough to ensure safe products.

**How FSMA Regulations are Finalized**

<table>
<thead>
<tr>
<th>Congress</th>
<th>Food and Drug Administration</th>
<th>Office of Management and Budget</th>
<th>Federal Register</th>
<th>Public Feedback</th>
<th>Final Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passes FSMA legislation</td>
<td>Drafts FSMA regulations</td>
<td>Reviews FDA’s draft regulations</td>
<td>Once approved, proposed rulemakings published in Federal Register</td>
<td>Public comment period for feedback to rulemaking takes place</td>
<td>Rulemaking may be changed by OMB/FDA, then becomes final rulemaking</td>
</tr>
</tbody>
</table>

**Where is it at Right Now?**

Among the Act’s more than 50 provisions, the legislation will require new safety plans from food companies, more vigilance from importers and inspectors, improved standards for produce, and more which we’ll discuss. The most vital rules were due on January 4, 2012, and the Office of Management and Budget (OMB), which oversees regulations, and the FDA recently published two of them (see below). So while implementation may be undergoing delays and some rules are being held up at the OMB, (and while many question the efficacy of the act) the legislation is still a reality and the FDA also recently received a budget increase to expedite implementation. And though the Tester amendment allows for the possible exemption of producers generating under $500,000 in sales each year, the Act will affect all food and beverage companies – not to mention international suppliers who will have to meet stringent new requirements to export food products to the U.S.

**Landmark FSMA Rules Published**

In early January 2013, two years after FSMA was signed into law, the FDA published two landmark food safety rules mandated by the Act. Measuring in at over 1,000 pages, the two lengthy proposed rules pertain to preventative controls and produce and significantly help round out the remaining regulatory holes in the legislation. The public is provided 120 days from the publishing of the rules to comment, before they are revised by the FDA/OMB and published as final proposed rulemakings and thereafter enforced. So, we can expect to see these two big pieces of the act enforced in mid-2013.
The Rules

What’s in Effect Now?

Not all facets of the legislation required protracted rulemakings to become a reality, so the FDA was able to achieve some new powers the moment President Obama signed the bill into law.

Mandatory Recall Power

It is surprising to some, but prior to the enactment of FSMA, food recalls were actually voluntary. The FDA could advise an organization to issue a recall if a product was deemed unsafe or if an outbreak occurred, but it was up to the organization to issue the recall or not. Naturally, from a business standpoint, a company would put itself at its own peril by persisting to market and sell a product deemed unsafe to the public, but now the power to order a recall is placed firmly in the FDA’s hands. If the Administration finds a “reasonable probability” food has been misbranded, adulterated, or capable of generating serious adverse health consequences, it can issue a mandatory recall.

Record Submission

Underlying the need for robust recordkeeping in the era of food safety modernization, this key provision enables the FDA to demand records of other affected food products if it finds a reasonable probability of serious adverse health consequences in any food product.

Whistleblower Protection

Mirroring what has been a key theme recently for the Occupational Health and Safety Administration (OSHA), the FDA’s counterpart in health and safety regulation, the FDA is establishing whistleblower protection as a cornerstone of its regulatory agenda. So while whistleblowers were protected to an extent previously, now those that report violations or testify benefit from increased protection from any form of reprisal.

Increased, Risk-Based Inspections

Almost all food and beverage companies have experienced an FDA inspection at some point. Now businesses can expect more inspections. In addition to increasing the frequency of inspections, the FDA now also uses a risk-based model to prioritize inspections. What exactly constitutes a ‘high-risk’ area has yet to be determined, but the FDA is in the process of defining risk categories.
Suspension of Registration

The FDA has the power to suspend a facility’s registration if it finds the facility’s food poses a “reasonable probability of serious adverse health consequences or death.” If your registration is suspended, you basically can’t do business.

First FSMA Rules

In addition to the above powers, which did not require rulemakings, the first two FSMA rules were finalized in July 2011:

Order on Detention of Food

This rule essentially gives the FDA the authority to hold products that may be contaminated or mislabeled. Previously, the FDA had the right to detain food when it had sufficient evidence it was mislabeled or contaminated. Now if the Administration even suspects contamination or mislabeling, it can detain a product.

And this rule has already been used. In August 2011, FDA inspectors found evidence of live and dead insects in food products at a food storage warehouse in Maywood, California. As a result, in the first application of the Order on Detention of Food, the Administration issued a detention order for spices, tamarinds, and chili products.

Rule on Imported Food

Companies importing food must now disclose whether any other country has rejected or refused a given product. While this may seem like a stroke of common sense, previously a U.S. food importer could receive and distribute food products already rejected by another country without advising the FDA.

Other

In addition to the above rules and FDA powers which all food and beverage companies ought to know about, the Administration has implemented a few other FSMA provisions to improve its capacity to target foods that may pose a risk to public health, including an anti-smuggling food strategy, a more consumer-friendly website for food recalls, and special guidance to the seafood industry – which will likely be designated high-risk – on food safety hazards.

Recent large-scale outbreaks and recalls were associated with:

- Eggs and egg products
- Cantaloupe
- Ground beef
- Cookie dough
What’s Coming?

A number of FSMA provisions that will have the biggest impact on food and beverage companies have yet to be implemented and while there is no specific timeframe for issuing the upcoming rules, the FDA has indicated that it is making significant progress. This fact is clear in light of the two sweeping, recently published rules mentioned earlier in this guide. Since a number of deliverables were due within a year of the Act’s signing on January 4 and are currently overdue (not to mention the lawsuits against the OMB and FDA), it can only be expected that the Administration is facing pressure to expedite progress and define requirements sooner rather than later.

Preventive Controls for Food Facilities

This is actually two separate rulemakings: one on preventive controls for facilities that produce and handle food to be consumed by humans and one on preventive controls for animal feed facilities. In light of the FDA’s new focus on prevention, these two rulemakings may be the single biggest component of FSMA and will perhaps impact businesses more than any other aspect of the legislation. A large part of these FSMA components are covered in the two recently published rules which will take effect later this year (a rule on feed facilities will be published shortly5).

When the rulemakings are finalized, these aspects of FSMA will ultimately require facilities to implement a system to identify hazards and establish a set of scientifically established controls designed to minimize risk. Food processors themselves will be responsible for establishing the controls, though the FDA will provide guidance on implementation as well as a self-assessment tool to help facilities determine whether they are in compliance.

When it is in full effect, all food facilities will have to comply by implementing a system of preventive controls. There will be some exceptions in the regulation for certain facilities based on their size and if they fall within a low-risk category.

Science-Based Produce Safety Standards

This component of the legislation specifically targets food safety in fresh produce and will set standards on farm-based growing practices and may be the very next FSMA provision. As of April 2012 the FDA indicated it was very close to publishing a rule on how food and beverage companies would have to comply with this facet of the legislation. What is clear is this rule will mandate organizations to implement hazard analysis and preventive control programs similar to what is demanded in the above preventive controls rules for facilities. Once again, part of these requirements are covered by the recently published rules.

FSMA is expected to cost $1.5 Billion to implement over 5 years.
Foreign Supplier Verification Program

It is no secret that a central premise in FSMA involves ensuring the safe quality of America’s substantial supply of imported food. As such, the Foreign Supplier Verification Rule will establish a system of importer accountability, ensuring that foods brought into the U.S. meet the same requirements spelled out in the facilities-based preventive controls programs outlined earlier in this section. It’s essentially a way of ensuring that international facilities that export foods into U.S. markets meet or exceed the same standards applied to U.S. facilities, thereby ensuring complete accountability and consistency across food supply chains.

Accredited Third-Party Certification

The Act also calls upon the FDA to develop a program to recognize accreditation bodies that will, in turn, grant accreditation to third-party auditors responsible for issuing key FSMA certifications, such as certification for the import of foreign food products. Food and beverage companies across the country will have to achieve certifications for certain activities, depending on the scope of their business. Accredited third-party auditors will be required to alert FSMA if they identify a condition that could lead to a public health risk during an audit.

What Else?

Most of the rules and requirements above are currently under review by the OMB and could see the light of day any time. Additionally, there are a few other FSMA provisions that will be rolled out in the near future, including:

- Revised good agricultural practices (GAPs) for produce.
- Guidance on preventing the intentional adulteration of food (bioterrorism).
- A national agriculture and food defense strategy that will be revised and updated every four years.
- Guidance on helping schools and childcare programs mitigate allergy risks.
- Designate what foods falls into the ‘high-risk foods’ category. As mentioned, businesses that fall in the high-risk category will face a higher frequency of inspections and more demanding recordkeeping requirements.
- The creation of five Integrated Food Safety Centers of Excellence at health departments.
Meeting Tomorrow’s FSMA Requirements Today

What’s interesting about many FSMA provisions is they are not unique. Certainly, this is the first time they will be legal requirements of doing business, but the essential framework of FSMA mirrors two similar sets of standards that have helped top-performing food and beverage companies ensure they are delivering the safest, highest quality products to the American people: Hazard Analysis and Critical Control Points (HACCP), a preventive approach, and Safe Quality Food (SQF), an international food safety management standard. Most food and beverage companies will need no introduction to these programs, which apply intensive, preventive controls to food production and handling in order to provide consistently safe food products to consumers.

FSMA vs. SQF and HACCP

With its emphasis on prevention, recordkeeping, inspections, and response capacity, FSMA virtually mirrors many aspects of the entire model HACCP and SQF (not to mention others) have established and, as incoming rulemakings are defined, it is widely expected they will echo the same essential principles that anchor these systems. As a point of clarification, HACCP refers to a systemic approach to food safety with an emphasis on hazards and critical control points, whereas SQF refers to a complete food safety management system standard that essentially includes the HACCP model within its umbrella of requirements.

If SQF and HACCP form the blueprint for existing and future FSMA requirements, it stands to reason that organizations that have achieved or plan on achieving compliance with either program – or at the very least mirroring their core pillars – will be better positioned to meet and exceed FSMA requirements as they take full effect. As a result, businesses that are proactively compliant will minimize the significant costs associated with noncompliance – costs tied to reinspections, forced recalls, brand damage, lost customers, or, at worst, being driven out of business.

...most food companies who are already familiar with HACCP, and have written food safety plans in place, will be able to easily comply.

Food Lawyer Shawn Stevens in Food Navigator-USA
**HACCP Central to Rules**

Many experts agree that HACCP is a cornerstone of FSMA requirements, and that food companies that have already implemented a HACCP-based system will be well-prepared for compliance. In January, Milwaukee-based food expert and lawyer Shawn Stevens told online food publication Food Navigator-USA, “I think most food companies who are already familiar with HACCP, and have written food safety plans already in place, will be able to easily comply.”

Another clue can be found in the fact that even before statutory deadlines for regulations, the FDA and the Office of Information and Regulatory Affair (OIRA, an office within the OMB) put forth regulations asking food companies to implement HACCP programs. So though these proposed regulations did not see the light of day before deadlines last year (many suspect the two organizations were hushed in the midst of a polarizing election where regulation was controversial) they do offer a lot of insight into where FSMA was headed at the time, and early reviews of January’s two sweeping proposed rules show that HACCP has been a guiding factor.

**FSMA's Four Pillars**

Like HACCP and components of SQF and ISO 22000, FSMA will have a core framework that rests on four key pillars. Each of these pillars can be addressed through a robust, HACCP-based food safety management system. Below we’ll take you through a high-level checklist of what your food safety management system needs to comply with FSMA rules.

**Preventive Controls**

As we’ve learned, the central theme in FSMA is proactive, preventive food safety management, and as expressed by the Preventive Controls for Facilities rule outlined earlier in this guide, having a preventive food safety plan and food safety management system is going to be one of the most business-critical aspects of FSMA compliance. It holds food companies accountable and positions them to prevent outbreaks of foodborne illness and resultant recalls, rather than responding to them.

But at its heart, building a robust, preventive food safety management system isn’t that complex and involves the following key requirements:

- **Hazard Analysis:** You’ll need to have plans in place to identify food safety hazards (any property or condition that may make food unsafe) in your facilities and determine preventive measures that can be applied to control these hazards.

- **Validation and Verification:** It’s great to have a Hazard Analysis plan, but it is no good if it is not working. You’ll need strong validation and verification plans and procedures that effectively ensure your system is working as intended.
Monitoring: This involves essentially defining the monitoring activities that will be undertaken to ensure defined critical control point processes are effective and provably under control.

Recordkeeping: This is a no-brainer. When FSMA is fully revealed, it is going to be absolutely integral for food companies to maintain comprehensive records. While paper records can be retained to attempt to meet recordkeeping requirements, this approach will be incredibly time-consuming, costly, reactive and fundamentally insufficient to meet FSMA requirements. Centralized, web-based document control solutions will be the most effective way to proactively manage compliance.

Corrective Actions and Performance Standards: Food companies must increase the volume, detail and availability of records related to monitoring, corrective actions and verification and these records must be provided to the FDA upon request.

**Inspection and Compliance**

Inspections could be considered the FDA's bread and butter in terms of holding industry accountable. There were more than 20,000 facility inspections conducted in the 2011 fiscal year alone, and that number is poised to increase substantially in coming years.

What you need to know:

There is an inspection frequency mandate that is based on risk:

- High-risk facilities will be inspected once in the first five years of the signing of the Act.
- These facilities will be inspected once every three years thereafter.
- Others (i.e. not identified as high-risk) will be inspected once in the first seven years of the signing of the Act, and once every 5 years thereafter.

Who is high risk?

- The recently published rules lay out criteria for considering high risk, so evaluate the rules closely to determine if you fall in this category.
- Chances are, if you are large importer of food, or if you produce or handle fish and seafood, you’ll be considered high risk.
- The Act allows the FDA to apply own knowledge from experiences to expand or adjust who is considered high risk.

Mandatory recalls:

- As mentioned, when the bill went into law the government was granted the immediate authority to force a recall of a food product.
- The commissioner of the FDA or the Secretary for Health and Human Services has the exclusive authority to mandate a recall, though industry can still voluntarily recall a product.
Important compliance provisions:

- The FDA now has an expanded administrative detention ability, something they achieved in 2002 but is now more sweeping under FSMA. It essentially enables the administration to detain food that is suspected to be associated with bioterrorism.

- The FDA also has the ability to suspend a registration, essentially disallowing producers from distributing a product from a facility where registration has been suspended. This applies to both importing and exporting products into/out of the United States.

Amplified sampling/testing:

- In addition to increased inspections, there will also be increased, more intensive sampling and testing of products.

- This has the potential to place an enormous load on laboratories, so some sampling and testing may have to be outsourced to accredited labs.

Accreditation of labs:

- The FDA is coming up with very strict guidelines for the accreditation of third-party labs.

- There will be more pressure on labs to detail and document inspections, and to do more inspections.

The whole idea behind many of these FSMA inspection and compliance aspects is that the Administration needs to be able to trace back exactly where food came from in the event of an outbreak and understand the analysis that was performed on the food product as it went through food supply chain.

Imported Food Safety

The more rigorous rules on food imports are rooted in expectation that food consumed is safe to eat regardless of where it comes from. In today’s global food supply chain, more and more food is imported into America: 15% overall, 60% when it comes to food and vegetables, and 80% of fish and seafood. And notably, imports are responsible for over half of foodborne illnesses. While it seems incredibly ambitious and complicated to extend American standards beyond U.S. borders and therefore across the international community, the Act was intended to establish controls and implement a uniform set of standards.

Countries exporting food into the U.S. don’t need to have standards exactly like FSMA, but their rules do have to be prevention based. So, how is the FDA actually going to ensure this? Through a

Imported food accounts for 15% of food in U.S.
variety of new requirements for importers to prove and verify that foreign suppliers are producing food according to this uniform standard.

What you need to know:

You are Accountable: If you import food, it is critical to know that the FDA will hold you accountable for the food you import, and for verifying your supply chain.

More Inspections: The FDA has a mandate to conduct more inspections on imported food.

Right of Refusal: The FDA also has the right to refuse the entry of food product from any firms that have refused inspection.

Import Certification: Accreditation guidelines will be implemented to enable third-parties to certify companies that import food.

Voluntary Qualified Import Program (VQIP)

The FDA will also implement a Voluntary Qualified Import Program (VQIP) to help importers achieve expedited entry of food into the U.S. through proactive compliance. While this program is not in place yet, regulations are required under FSMA to be finalized by July 4, 2013.

When VQIP is in place, you’ll be able to apply to the FDA by providing foreign facility certification that shows imported products adhere to standards greater or equal to those of the FDA’s. If successful, you’ll be able to import food faster.

Response

The fourth pillar upon which FSMA rests relates to response capability, the other side of the prevention coin which is so central to the Act. While the intent of FSMA is to make America’s food safety system all about prevention, the possibilities of recalls and outbreaks will unfortunately always remain.

As the most regulation-light facet of the Act, many provisions laid out in the response component of FSMA have already been implemented and enforced. Revisit the “What’s in Effect Now” section of this paper for a rundown of the key elements of FSMA’s response powers, including:

- Mandatory recall powers.
- Expanded administrative detention.
- Record submission.

In addition the FDA has also launched a product tracing project that will enhance its ability to track and trace both domestic and imported foods, and is also implementing additional recordkeeping rules for high-risk foods.
The Essential Guide to the Food Safety Modernization Act

The Role of Technology in Compliance

While FSMA seems incredibly sweeping and complex, what you might have gleaned over the pages of this guide is that so much of the Act is all about recordkeeping. Records for inspections. Records for preventive controls. Records for certification. Records to keep up to date. Records to access instantly. Records to submit. Yes, there’s a lot that is required beyond documentation, but behind every process improvement, behind every certification, behind every corrective action, there’s a document. And under FSMA provisions, when the FDA asks a food company for a record, they ought to be able to submit it. Quickly.

Historically, food and beverage companies have attempted to implement a food safety management system with paper, yet this is an archaic method of approaching compliance and improved food safety, not to mention a perilous way to try to do business in the food and beverage sector. But above and beyond past food safety requirements, it would be foolhardy to try to comply with the far more rigorous requirements laid out in FSMA with a paper-based system, or even standard, out-of-the-box word processor or spreadsheet programs.

That’s why businesses across the industry are increasingly turning to streamlined, centralized software alternatives. With an electronic food safety management system, businesses with multiple sites and a nationwide or global reach can effortlessly access the same, most up-to-date records, requirements and other critical food safety metrics within one centralized repository. Traditional systems with disparate, siloed software products (e.g. a word processor, a spreadsheet program) that aren’t fundamentally suited to the proactive and immediate demands imposed by FSMA, or worse, no software at all, hamstring food companies from meeting the rigorous requirements of FSMA and existing food safety management standards.

Under FSMA provisions, when the FDA asks a food company for a record, they ought to be able to submit it. Quickly. That’s why businesses across the industry are increasingly turning to streamlined, centralized software alternatives.
The matrix below compares the relative preparedness levels for food and beverage companies with respect to their existing information management tools and food safety management systems. Best-in-class companies that have already achieved SQF certification or rolled out a HACCP program almost always leverage specialized software tools to meet the array of requirements driven by these programs.

## FSMA Preparedness Risk Index

<table>
<thead>
<tr>
<th>Information Management Tools</th>
<th>Streamlined, Centralized, Web-Based Management System</th>
<th>Somewhat Prepared (adopt a FSMS)</th>
<th>Somewhat Prepared (adopt a FSMS)</th>
<th>Very Well-Prepared</th>
<th>Extremely Well-Prepared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Word Processor, Spreadsheets, Sharepoint (or equivalent)</td>
<td>Unprepared</td>
<td>Unprepared</td>
<td>Somewhat Prepared</td>
<td>Meets Minimum Standard</td>
<td></td>
</tr>
<tr>
<td>Paper</td>
<td>Very Unprepared</td>
<td>Unprepared</td>
<td>Somewhat Prepared</td>
<td>Somewhat Prepared</td>
<td></td>
</tr>
<tr>
<td>Little to No Documentation (no defined system)</td>
<td>Extremely Unprepared</td>
<td>Very Unprepared</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>No Food Safety Management System</td>
<td>Ad Hoc System Partial Structure</td>
<td>SQF Level 1 &amp; 2 HACCP-based Methodology</td>
<td>SQF Level 3 or equivalent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Food Safety Management System (FSMS)**
Be Prepared

If you operate in the food and beverage industry in the U.S. or work outside the country and export food to America, your business will be affected by FSMA. How dramatically you are affected depends on how you have approached food safety management, and what tools you have leveraged to ensure complete, sustained compliance.

Revisiting the key points of this guide:

• The Food Safety Modernization Act was legislated to address a rapidly increasing amount of food recalls, foodborne illness outbreaks, and food-related illnesses and deaths, and to counter the resultant degrading confidence in the American food safety system.

• While there have been some doubts about whether or not FSMA will actually become a reality in light of the very slow pace of its implementation, the publication of landmark FSMA rules among other telltale signs including enforcement of some of FSMA’s key provisions, demonstrate the Act is here to stay and will be in full force in the coming months.

• Depending on your level of preparedness, FSMA has the potential to help food companies improve their commitment to food safety and public health – but it also has the potential to impose steep fines and possibly put companies out of business, permanently.

• A number of FSMA provisions are already in effect (e.g. record submission), other rules are published and open to public comment before being finalized and enforced (e.g. preventive controls), while a few other elements are still in the rulemaking stage, with deadlines forthcoming.
About Intelex

Intelex provides web-based software that helps scores of food companies across the U.S. and around the world ensure the highest level of food safety and complete, sustained compliance with food safety regulations. We offer prepackaged HACCP-based software and complete Food Safety Management System solutions. Our scalable, web-based software benefits from over 20 years of experience and our suite of EHS, quality and business performance applications have helped clients across a diverse range of industries ensure sustained compliance with internationally accepted standards (e.g. SQF, HACCP, ISO 9001, ISO 14001 and OHSAS 18001), as well as all regulatory requirements. For more information, visit our food and beverage page and review a list some of our clients in the food and beverage industry, including Kraft, Nestle, Campbell’s, and Heinz.

We offer prepackaged HACCP software and complete Food Safety Management System solutions.

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Some of our clients in the food and beverage industry:
Endnotes


4. “FDA issues first new rules under Food Safety Modernization Act,” EPA News Release, August 18, 2011,


