SPEEDING UP FSMA COMPLIANCE:
10 QUESTIONS TO ASK WHEN YOU AUTOMATE
As most execs in the food industry already know, September 2016 is the deadline that the Food and Drug Administration (FDA) has set for starting to enforce many broad-reaching new food safety requirements and regulations under the Food Safety Modernization Act (FSMA). The stricter rules have driven many to start automating their processes, but have also left even savvy senior execs wondering how to prioritize when they update their systems for FSMA compliance—especially since the FDA will be phasing in new requirements over time. The good news is that early adopters are already far along in automating, and some are sharing what’s essential—and what to avoid—when seeking a solution to streamline compliance.

New urgency: Penalties aimed at executives
The stakes are high. Central to the FDA’s tougher approach is a no-excuses attitude toward affected companies’ management, who can be held liable for violations. Ignorance of the law is not an acceptable excuse and executives can be held liable even if they had no direct knowledge or intent. (Think Sarbanes-Oxley for food companies.)
“To have a successful quality program, you really need to be able to have both a facility view as well as an item-level view.”

—Ahmet Hepdogan
VP of Global Procurement and Supplier Quality
Ferrara Candy Company

What you can learn from early compliance leaders
But if you’re feeling a little overwhelmed at your early efforts—or maybe you’re falling behind in implementation—here are some important facts and lessons learned from advanced adopters.

Cloud solutions, automation speed up FSMA compliance
Depending on your situation—and with some good choices—you might be able to automate away much of the work, so you can “manage by exception.” The right automation can greatly simplify task assignment, collect documentation and assessments, easily generate reports and dashboards, and identify and flag other compliance issues. If you’ve already tried to automate some compliance tasks and haven’t been happy with either the results or the progress you’ve made, it might be time to consider a new approach. For example, the right cloud solution can be set up and deployed relatively quickly—delivering immediate benefits while driving compliance.
What are the biggest challenges to compliance?
Of course, most companies have been improving their food safety procedures for a long time, driving both their program and their trading partners to comply with a range of requirements. For instance, many companies already conform to existing HACCP requirements for food safety. But HARPC (FSMA’s Hazard Analysis Risk-Based Preventive Control requirements) adds additional new preventive controls that are driving the need to automate more compliance tasks.
Among the many changes that come with this new emphasis on prevention, each facility is required to:

- Evaluate hazards that could affect food safety.
- Identify what preventive steps, or controls, will be put in place to minimize or prevent the hazard.
- Describe how these controls will be monitored for effectiveness.
- Maintain routine records of such monitoring and testing.
- Specify what actions the facility will take to correct problems that might arise, including recalls.

These preventive controls requirements are just part of a new focus on documentation and monitoring that poses big compliance, IT and quality assurance headaches for many companies. These problems are magnified by the requirement that compliance records need to be kept for up to two years, and available to regulators within 24 hours of request.
Getting Started
A Practical Approach to FSMA Compliance

Connect to your trading partners and automate collaboration
• Collaborative network for efficiency
• Centralized repository for information storage, access and sharing

Conduct your assessments-trading partner/product, foreign supplier, internal program, etc.
• Collect supporting documents (HACCP & HARPC plans, past audits, SOPs, etc.)
• Self assessments – Preventive controls/food safety plan, FSVP, food defense
• Analyze results, score & benchmark trading partners, segment markets

Create and implement plans/program - Food Safety (HARPC), FSVP, Food Defense
• Incorporating completed assessments, documentation
• Evaluate, assess, determine approach/prevention plans, monitor and adjust procedures

Monitor, verify and manage program – approach depends on risk, your assessment/plans
• Document collection – audits, tests, COAs, etc.
• Conduct audits, perform tests and evaluate
• Implement corrective actions & adjust plans where needed

Manage by exception, not by emergency
But the right technology can automate much of this huge information-management problem, helping companies manage by exception, says Ahmet Hepdogan, VP of global procurement and supplier quality for Ferrara Candy Company, who chose ICIX to help him manage compliance for the worldwide food brands company.

“You give the control of the information to the user. You can extract what you need very quickly.”
—Ahmet Hepdogan
VP of Global Procurement and Supplier Quality
Ferrara Candy Company

Having easy-to-interpret, automatically updated information at the fingertips of everyone in the process is critical. “Out of five facilities that make candy, every user has the capability of logging in directly from their desktop,” says Hepdogan.
What should you look for in a FSMA compliance solution?
Companies that are successfully implementing FSMA say that the following questions are important to ask to get the right solution for your company.
Automating FSMA Compliance: 10 Critical Questions to Ask

1. Does the solution manage information on BOTH trading partners AND products?

Some systems are only designed to track one or the other. For true transparency and risk evaluation, you need insight into trading partners and products, so that you can understand the relationships among products and suppliers. You want one system that has the flexibility and transparency that comes from handling both, so you don’t create new “information islands” that are difficult to navigate or require lots of time and expertise to integrate.

2. Does the solution have an extensive network?

Preferably, it already includes many of your current trading partners—your suppliers, customers and any critical third parties such as certification bodies and scheme owners. For example, ICIX has more than 20,000 trading partners on its Active Transparency network. Your strategic partners could be among them, making it even easier to collaborate on common compliance issues, and leverage work that’s already been done. So always check before you choose.

3. Is it strategic?

Pick a solution that solves a broad scope of related problems. It should interact easily with the systems you already have, to share information and leverage existing investments. A good FSMA compliance solution should also be able to help with other compliance issues, as well as recalls, collaboration with trading partners, product labeling and most aspects of quality assurance management.

4. Can the solution take inputs from many sources, including certification bodies and scheme owners?

Some systems are directly updated with audit results from validated third-party sources, so you never have to worry about whether the information in your system is accurate or current. Also, some solutions let users communicate with non-subscribing partners, and some don’t.
How easy is it to gauge your compliance in real time?

Look for transparency into most or all of your processes and importantly, your trading partners. For example, missing or incomplete hazard assessments or mitigation plans should be obvious in whatever system you use.

The best solutions can give you a current view of all of the products, trading partners and relationships in your supply chain—and update them automatically when they change—a feature that ICIX calls “Active Transparency.”

Can the solution handle new requirements with ease?

Food safety regulations change often. FSMA enforcement will become increasingly strict through 2020, and FSMA is not the only set of regulations and requirements that food-related businesses must meet. Enhanced nutritional panels are just one pressing example. So whatever solution you choose, it needs to be flexible and easily extended to meet new requirements.

Does it supply dashboards and alert facilities that help you manage by exception?

Ideally, you can just “set it and forget it,” and get automatic alerts of the possibility of a problem. And it should be easy to look at a dashboard or alert and quickly respond to the situation that it portrays.

How does the solution handle updates, upgrades and new requirements/features?

Here the choice is between a cloud solution and either a homegrown or on-premise system. If you go for a do-it-yourself solution, you need to plan budget and manpower to regularly modify your IT infrastructure to handle the changes. Cloud solutions don’t require you to handle maintenance or upgrades, but you’ll want to evaluate how easy the cloud provider is to work with, how stable it is, and how likely the provider is to invest in frequent upgrades.
How hard is it to integrate with the rest of your strategic information technology?

The best solutions fit with your existing infrastructure, so pick solutions that work with standard platforms and enterprise technology. Don’t make the mistake of selecting a niche solution that creates another isolated data island and adds to the complexity of your IT infrastructure. ICIX, for example, is built on the Salesforce platform. (Salesforce is known mostly for its market-leading customer relationship management system, but it’s also the leading cloud platform for developing enterprise applications.) So if you’re already running Salesforce, it’s a great fit. And if you’re not, it’s engineered to be compatible with most common enterprise technology, so it still works well with what you already have.

How easy is it to ramp up?

Look for templates and best-practice frameworks that can be quickly tailored to help to bring your organization up to a high standard of compliance—quickly.
Automating FSMA Compliance

The Takeaway

The new FSMA rules are wide-ranging and challenging, affecting many different businesses. But smart executives and managers can tackle them with technology that automates much of the paperwork and lets you manage by exception.

Click here to learn more about how a cloud-based FSMA compliance solution can help you meet the new FSMA requirements—and better manage your business relationships with your trading partners.