

## Tracking and Traceability

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Playing Together to Link the Chain

Regulations are tightening on tracking and traceability.

Although the Bioterrorism Act of 2002 initiated some new requirements for one forward/one back tracking of the food chain, it was fairly lenient on how traceability was conducted, said LogicQ President Andrew Kennedy. And now, as the provisions of the Food Safety Modernization Act (FSMA) gradually roll out, Kennedy said, “Those days are over.” That leniency is rolling right out of the chain, and food manufacturers need to be prepared to comply.



“There’s been an unbelievable change in the power dynamic,” Kennedy said. It used to be that FDA had to have reasonable suspicion of adulteration. Now any officer or qualified employee can conduct an inspection of your plant and have product held if he or she sees any potential for suspicion. “They used to have to have reasonable suspicion that a product was adulterated. Now they’re free to go fishing,” he said.

Reiterating Kennedy’s phrasing, Christian Hutter, Junction Solutions vice president of food & beverage, said, “There’s an increased control that will happen with FSMA, and increased inspections. There will probably be more recalls and ‘fishing’ expeditions.”

While the FDA has not yet released specific regulations or compliance guidance, much of FSMA focuses on preventive controls, said Gay Whitney, senior vice president of industry engagement, GS1 U.S. “[It] also requires that all players in the country’s food supply chain be able to quickly trace from whom they received a food product and to whom they sent it.”

And to enable that, Kennedy said, “Everyone has to play together.”

Today the key words in traceability are standardization and electronic systems. Not only are manual, paper-based systems slow, causing issues for both consumers and the companies themselves that are subject to even tighter hold potential, but also, Kennedy said, the FDA simply does not have the manpower to work with manual trace backs or try to connect systems that don’t “talk” to each other from one chain link to the next.

It is very difficult to work with manual or spreadsheet-based systems, said Katie Dowling, a senior solution consultant at Sparta Systems. “There’s no way to prove changes or updates; and in FDA inspections, that’s what they will be looking for.”

“Recordkeeping will be critical,” she said. “If you can’t produce it quickly, your life will get

more and more miserable as they will continue asking for more and more information.”

The general mandate, said Christian Hutter, Junction Solutions vice president of food and beverage, is to shorten the cycle; to prevent unsafe foods from entering commerce and protect the consumer. “We need a better, faster, more complete way to do traceability,” he said.

### **Five Steps in a QMS Review**

*by Cathy Crawford, HACCP Consulting Group, and James Dobbs, Qualtrax Inc*

A thoroughly documented food safety system with validated preventive controls (a HACCP plan) is the best means to avoid unnecessary detention. This can only be achieved with appropriate training, organized record-keeping systems and process management to ensure consistent enforcement of policies. Companies should review their food safety plans or have a third party do so, paying specific attention to record-keeping to ensure communication of accurate and complete data. Electronic quality management systems (QMS) are highly encouraged, based upon the potential for human error and costs associated with managing a system of manual controls.

When reviewing a data system, consider the following:

1. If an activity has an impact on food safety, it should be recorded. For example, lack of evidence of appropriate use of sanitizers combined with the presence of a strong odor could lead to “reason to believe” that the product is adulterated.
2. The frequency of recorded events should be related to food safety and process stability. Be prepared to consider the product or process from the time of an “out-of-limits” event back to the last acceptable check as unacceptable. For example, if a company checks temperature once per hour, all production for up to one hour could be suspect if the process is discovered to be out of limits. If

**Standardization.** As a part of FSMA, the FDA is focusing first on areas and foods of highest risk, Dowling said. “The FDA is trying to bucketize what is high risk, and produce is at the top of that list.” Produce is also an area of the industry that has been focusing on traceability, and has, in fact, moved ahead of FSMA; a fact recognized by the FDA.

“The Produce Traceability Initiative (PTI) is in sync with the Food Safety Modernization Act,” said Elliott Grant, CMO and co-founder of HarvestMark. In fact, he said, the FDA is using the produce industry as a test case and a traceability model for the food industry.

As such, the industry standard is very likely be based on GS1, the global standard that is the backbone of the current retail barcode system and that advocated by the PTI. “The initiative provides practical, useful information and tools, and is designed to help members in the fresh produce industry maximize the effectiveness of their current traceability efforts,” Whitney said.

In addition, she said, PTI outlines a course of action to help companies implement case-level traceability by linking their internal traceability systems to an external system.

Utilizing such bar codes also makes it easier for consumers to know if their food is infected, Hutter said. “One issue we see is the timeline between the identification of an issue and it being pulled from the shelf. It needs to be quicker, because of lot of times, it’s already consumed,” he said. Faster tracing through any food chain is also significant, “so people aren’t avoiding tomatoes when the culprit is peppers,” he said.

This also validates the need for systems to mesh across food types. “We need to make sure initiatives in one [food] industry mesh those in others,” Kennedy said. “You can either link the chain proactively before there’s a problem, or you can link it reactively after it happens.”

**Beyond Form to Function.** While it is critical for the systems to be able to talk across the chain, there are also areas on which plants can focus within their own processing systems to ensure they have a foundation for compliance as traceability regulations roll out. This can be thought of as a

the same checks are once per shift, up to eight hours of production would be suspect.

3. Records are to be completed in ink or electronically (21 CFR part 11) at the time of the event by the person conducting the activity.
4. Each recorded activity should include either affirmative or negative results accompanied by the signature or initials of the person who completed the action. Record evidence of compliance or control as well any noncompliance. For example, a daily sanitation inspection should document acceptable conditions as well as unacceptable ones.
5. After a corrective action, always document a return to control or appropriate conditions. For example, documentation of unacceptable sanitation should be followed by documentation of re-cleaning and re-inspection including the results of that inspection.

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four-step process:

1. **Define.** How do you define lot size? How do you address comingling? And—what do you have in place for certification, such as SQF or Global Gap, for both yourself and your suppliers? “Those are some of the control points you need to be sure you have in your facility,” Hutter said.

When it comes to comingling, however, Dowling affirms that “that traceability factor is going to get tricky.” Bakeries often have silos of wheat or flour in which multiple sources are comingled.

While this may make it impossible to trace a loaf of bread to a specific source field, “know which suppliers and lot numbers are in each silo,” she said. “At least be able to trace back to a handful of suppliers.”

2. **Evaluate.** How do—or would—you currently perform a recall? How do you know that you recalled everything? Can you quickly access your records? “You hold your own data,” Grant said. “In the event of a recall, the FDA has the authority to request your data.” And will want that data to be accessed quickly, accurately, and up and down the chain.

3. **Document.** What, exactly, does your recall system look like? Can you show it to FDA? While implementing a new, electronic system with automatic documentation can be expensive, the financial impact of having product held because you cannot document your product’s safety can be significantly higher. Thus, Hutter said, “It is imperative, so that your operation doesn’t come to a standstill.”

“You need to have lot definitions and lot segmentation schemes,” Kennedy said, including, “documenting and defining lot code and where your breaks are.” In addition, you need to have legally defensible evidence backing up your documentation. “If you don’t have that, then lot traceability doesn’t make any sense.”

4. **Test.** Once you have your definitions, you need to integrate testing into that, Kennedy said. Pathogenic, chemical, and/or physical testing should synchronize with your lot definitions and lot breaks.

Then test the whole program with mock trace back and trace forward to ensure you have clear segmentation and traceability. “That’s something that people can do today,” Kennedy said. “And that’s just good business practice and food safety procedure regardless of how the law shakes out.”

**Prepare and Comply.** Although FSMA’s directive to increase FDA inspections focuses on a

gradual roll out, “you may as well start now, because it’s going to come,” Dowling said. Even if it is not yet absolutely required, FDA is looking for quicker tracing and has the authority to institute repercussions when there is any doubt. And while the fine print of the directives may be complex, traceability compliance is also quite simple, Dowling said, “Get your records in order, and be able to access them quickly.”

But even as plants seek to comply with FSMA, it can be advantageous to look beyond the minimum requirements, Grant said. “The more forward-looking producers are saying, ‘How can we take advantage of this to make our processes even better?’”

Grant equated it to the evolution of the Internet. Even once people realized the advantages of a world-wide, common-language connection, few could anticipate the vast range of sites and services that would develop from it, Grant said, citing Google, E-Bay, Groupon, etc. In the same way, he said, “We can’t predict all the innovative things that will happen from this.

“It’s a huge undertaking, but we have a path to follow,” he said. “The opportunity lies in not seeing this as a one off, but as a platform of improvement for the whole supply chain.”

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