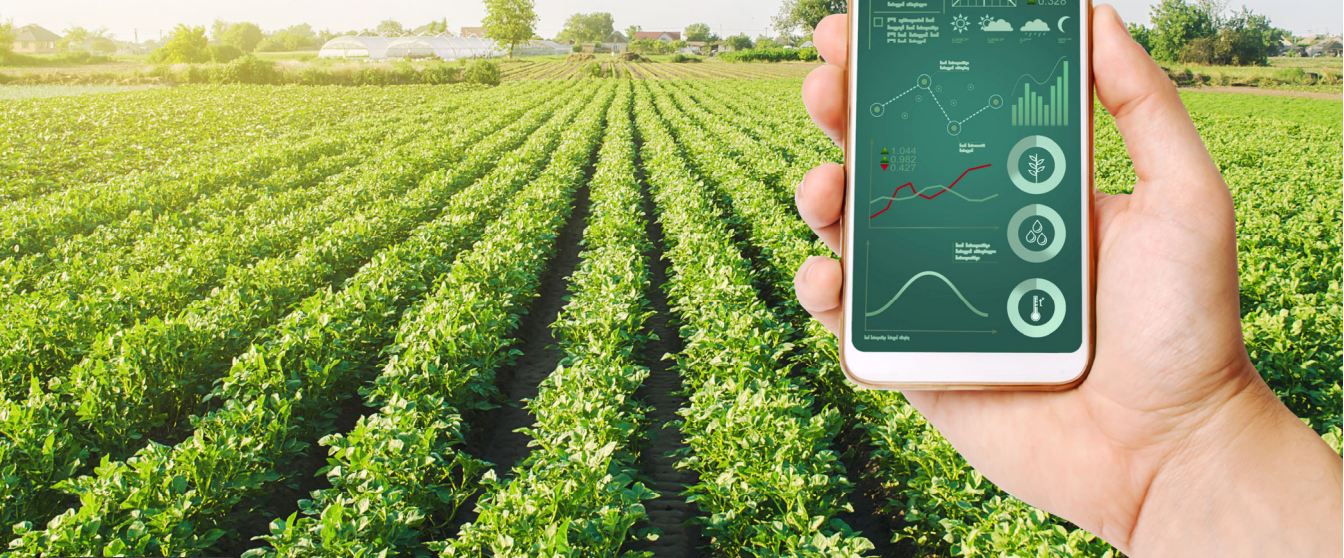


How Will FSMA Affect The Supply Chain



By Paul Damaren

Food safety has long been one of the issues that keeps CEOs in the food industry awake at night. They are worried not only about the risk of recall, but also potential supply chain and process mishaps by personnel who handle their products. The FDA's upcoming FSMA 204 regulations stretch beyond routine sanitation requirements, cleanliness standards and typical government regulations. In short, if FSMA 204 and food traceability isn't on your radar already, it needs to be now. Here's why.

Better transparency for consumers, faster recalls for the industry.

There is an increasing demand from consumers to know where their food comes from— from sustainable sourcing and growing practices to being in-the-know when a product is recalled. The industry needs a faster, easier and less expensive way to do recalls. Today's processes take weeks or even months, when it could take minutes.

To this end, the federal government is enacting new regulations that will require food manufacturers, processors, retailers, wholesalers, foodservice and other companies to track certain key data elements (KDEs) during different points in the production process also known as a Critical Tracking Event (or CTE). These requirements will impact only those companies responsible for items on the Food Traceability List (FTL), which includes 16 major categories like produce, finfish, shell eggs, ready-to-eat deli salads, cheeses, and nut butters. Most of these products can be found throughout the supply chain and are common ingredients – especially in restaurants. The regulation encourages companies to use this system voluntarily for now, but the bottom line, this is going to affect almost everyone.

Take a closer look at the new regulations.

While federal regulations provide some guidance through HACCP (Hazard Analysis Critical Control

Point), state governments have imposed even more stringent rules designed specifically for protecting consumers from bacterial infections. Local communities should be aware too: many cities will require businesses to meet specific standards in order to continue doing business there.

In response to the growing automation in retail supply chains and increased data tracking, many leaders have made product traceability a priority and that's a good thing! These companies are seeking benefits from an ROI model by implementing better inventory management as well as faster recall processes that will create transparency throughout their entire business networks. They feel it's worth the investment because of the potential return.

The FDA is required, by virtue of a consent decree signed in US federal court, to publish the new rules for end-to-end traceability of high-risk foods on the FTL by November 7, 2022. For every FTL item provided by a supplier, on every shipment, to every DC and down to every restaurant, suppliers and receivers will need to create a shipping Key Data Element (KDE) record for every Critical Tracking Event (CTE) with traceability data including the batch/lot code.

This information must be retrievable to present to the FDA on demand, in a sortable spreadsheet within 24 hours. This will require the collection and management of potentially millions of records per year for QSR operators and their suppliers.

The new rule, which was released by the US FDA in their New Era of Smarter Food Safety initiative aims to move beyond current "one-forward/one back" traceability that requires all trading partners such as farmers, restaurants and retailers to record where product came from or were going. This builds on multiple technologies like analytics tools for tracking food products, while also looking at use cases including creating digital platforms where consumers can buy directly from farmers without any middleman interference.

Now, the FDA has taken an important step towards ensuring food safety by requiring companies to implement digital traceability systems beginning this year, November in fact – FSMA 204. The new legislation is part of FSMA (the Food Safety Modernization Act), which was passed into law in 2011 and marks another landmark achievement for the agency's mission: To protect the public's health through strong regulations on foods ranging from produce and prepackaged products at grocery stores all way up through processed meals found in restaurants or hospitals alike.

The path toward true end-to-end food traceability

On September 21, 2020, the FDA released a proposed rule to accomplish traceability in the food system from the farm to the table. The requirements, which are expected to go into effect in November 2022, will help the FDA rapidly mitigate foodborne illness outbreaks and other negative health consequences. The FDA proposes rules under section 204(c) that would provide greater insight into where your dinner came from - right down to the farm.

According to FDA regulations, FSMA 204 establishes “additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons and companies who manufacture, process, pack, or hold foods with 10 or more employees. The FDA expects that data will be available within 24 hours of a request, making paper recordkeeping an improbable task for most companies.

The approach to traceability enabled by this law creates transparency needed for anticipating and preventing supply chain disruptions in public health emergencies without electronically recording every product detail at each step along the journey like before FSMA 204 came into effect. The FDA encourages trading partners to use new digitally-enabled technologies and data sharing that greatly reduces the time required for traceability. This rapid response helps prevent disruptions in a public health emergency, while also creating transparency needed when anticipating issues within one's supply chain.

The FDA is encouraging firms to voluntarily adopt tracing technologies and ways of harmonizing their activities, which will support interoperability across a variety of technology solutions. This proposition has been accomplished through incentives for better tools as well as data standardization that creates greater visibility into supply chains while also detecting challenges sooner than ever before with accuracy.

Label-scanning of cases works in certain parts of the food supply chain, but is cost prohibitive in high-throughput DC environments. Investments in new hardware and process changes would translate into higher operating expense, which would ultimately be passed to stores and consumers in the form of higher prices.

Choosing technology that enables traceability compliance with little to no additional expense, no new hardware investment and minimal process change is the key to widespread traceability adoption.

What's the cost?

FSMA 204 compliance can increase costs for all trading partners, but it doesn't have to. There is concern that the requirement of new technologies like lot code scanning and production information capture could impact a company's budget as well as their ability in terms data management; this would be an additional worry if we're talking about huge amounts - which seem inevitable with today's technology advances.

Supply chain digitization and product tracking have long-lasting business impacts by delivering safe food with little to no increase in cost. They also help with identifying risks, building brand reputation and controlling food safety incidents. To take advantage of these opportunities, several food retailers and wholesalers supported by ReposiTrak, formed the Food Traceability Leadership Consortium (FTLC) to help food retail industry leaders collaborate on the development of a common and scalable food tracing solution. During its inaugural meeting last year, the FTLC established three principles to guide the response to the potential expansion of food traceability requirements:

- Minimal cost that doesn't impact margins or price to consumer.
- Easy to adopt, use and verify in order to drive universal adoption.
- Meet or exceed FDA-proposed regulations to prepare for the future.

It's important to note that even without the push of the FDA and FSMA, traceability is seen by the extended retail supply chain as increasingly desirable to speed up recalls, re-create transparency, allow better inventory tracking and more. Several leaders in the industry, including Walmart and Amazon, have made product traceability a mandate and are pursuing a series of benefits to create an ROI model for it.

"The ultimate reward to the business and the industry at large is greater visibility into the supply chain, and the ability to accelerate recalls. Our customers are looking to not only meet but exceed the new FDA traceability requirements and they want to do it swiftly and accurately at an extremely low cost and with minimal operational disruption or process change" said Paul Damaren, Executive Partner, ReposiTrak.

The ReposiTrak Traceability Network Solution

With the direction of the FTLC, ReposiTrak developed the Traceability Network (RTN). It is built on the company's existing, proven technology platform that electronically collects and stores shipment data from existing supplier systems at each CTE. The RTN creates an electronic pedigree of each product and each transfer.

Because the solution leverages existing ReposiTrak technology and the facility network mirrors the food supply chain, the cost is spread across the network to deliver a solution that is easy to adopt and affordable for even the smallest suppliers. And, because the RTN currently comprises over 110,000 supplier facility connections today, the majority of suppliers of high-risk products are already connected to the ReposiTrak platform for document and data sharing.

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For more information

Food & Drug Administration—FMSA link:
<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>