



What We've Learned From The FDA's New Era Of Smarter Food Safety And How It Will Impact What's Coming Next

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FDA's New Era of Smarter Food Safety

Food Safety Modernization Act (FSMA), which was signed into law in 2011, is intended to help maintain the safety of both human and animal food during manufacturing, processing and transportation. It is comprised of seven major rules.

1. **Preventive Controls for Human Food** – Human food facilities registered with the FDA must implement a written plan that identifies hazards and outlines appropriate preventive controls.
2. **Preventive Controls for Animal Food** – Animal food facilities registered with the FDA must implement a written plan that identifies hazards and outlines appropriate preventive controls.
3. **Produce Safety** – Establishes minimum standards for growing, harvesting, packing, and storing produce.
4. **Foreign Supplier Verification Program** – Importers must verify that their global suppliers comply with FDA regulations.
5. **Third-Party Certification** – Accredits third-party certification bodies to administer voluntary consultative and regulatory audits to help companies prepare for regulatory audits or achieve certifications.
6. **Food Defense (Intentional Adulteration)** – Food facilities registered with the FDA must develop a plan that assesses contamination vulnerabilities and document a mitigation strategy for each vulnerability.
7. **Sanitary Transportation** – New requirements for companies that transport food, including shippers, receivers, loaders, and carriers.

In order to further improve on food safety and preventive measures, FDA released a “Blueprint for the Future” to the food processing industry in July 2020.

The blueprint outlines the approach FDA will take over the next decade to usher in its New Era of Smarter Food Safety.

The blueprint covers the food processing ecosystem from the water used to grow crops to the last mile of home delivery. It includes but is not limited to the perspectives of:

- Product: importance of food safety and traceability in products and in processes.
- People: critical nature of operator safety and overall operational excellence.
- Business: holistic approach to food manufacturing for profitable business and growth (such as productivity improvement, cybersecurity, inventory control, automation, supply chain resiliency, and more).

Or, as the FDA describes it, people-led, FSMA-based and technology-enabled.

According to the FDA, many people believe we will see more changes in the food system over the next 10 years than we have over the past several decades. Foods are being reformulated, new foods and new food production methods are being realized, and the food system is becoming increasingly digitized. Since the blueprint was released, much has changed, in many ways driven by the COVID-19 pandemic, and the FDA has given us glimpses into what might be coming next.

For example, the FDA recently announced a “low- or no-cost challenge” inviting technology providers, public health advocates, entrepreneurs, and innovators to develop traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end-user. The obvious goal is to advance food-related technology, but also to do so in a way that lowers barriers for manufacturers to adopt such technology.

Essentially, the FDA is creating a modernized food safety regulatory framework while also leveraging the use of new and emerging technologies and approaches.

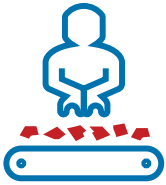
They are encouraging stakeholders to tap into artificial intelligence, the Internet of Things, sensor technologies, and blockchain to strengthen predictive capabilities, accelerate prevention and speed outbreak response.

This white paper is based on insights from food safety experts in the Manufacturing Extension Partnership (MEP) program, a national network with hundreds of specialists who understand the needs of America’s small and medium-sized manufacturers. The MEP National Network consists of MEP Centers located in all 50 states and Puerto Rico. MEP provides companies with training and resources to enhance growth, improve productivity, reduce costs, and expand capacity.

MEP food safety experts provide context on what’s been learned since the blueprint was released and what may be coming next through the lens of the FDA’s four pillars for the New Era of Smarter Food Safety:

- Tech-Enabled Traceability
- Smarter Tools and Approaches for Prevention and Outbreak Response
- New Business Models and Retail Modernization
- Food Safety Culture

Pillar 1: Tech-Enabled Traceability



The Current Traceability Model Doesn't Scale

According to the FDA, the records involved in moving food through the supply chain are still largely paper-based. This, along with insufficient data identifying the product along the supply chain, creates an inability to rapidly track and trace food for recalls. Traceability in its current form does not scale.

The industry is not as advanced technologically as it needs to be. A food recall may only be as good as the weakest link in that food chain. As a result it can take days to months to figure out sources of issues, which heightens related issues for removing inventory and greatly increases the related costs of a product recall.

This reality aligns with what MEP Centers experience on the front lines. Examples of the tech gap that limit tracing include:

- Lack of industry standards for tracking at key points in the production and supply chain.
- Lack of standards for key data elements. Regulations do not specify the details of use for date and batch codes, but they do require a mechanism to be in-place for traceability. Sometimes manufacturers use one approach; sometimes the other. But the lack of a comprehensive requirement to use both date and batch code data has slowed the adoption of this best practice.
- No standard for digitization and connectivity. Some small manufacturers have not digitized any of their operations; some in rural areas lack internet capabilities needed for block chain or a digital technology platform. Many manufacturers deal with software systems that don't talk to each other.

Advances in detection technologies and epidemiological networks are facilitating the identification of potential sources of contaminated product. We now live in an age in which we can find traceability in pathogens that make us sick, but we lack the science and technology to trace our ingredients. This dynamic makes it essential for the industry to modernize prevention, quickly identify contaminated food, and help to ensure that it is removed from the marketplace.

Technology exists for a more finite tracing process. But it will take agreement on standards and changes in behaviors, processes and tools to track information on:

- What equipment was used
- What people were involved
- What ingredients are used in the product
- What processes were used
- What was the original source of the ingredients

Removing Barriers Starts With Incentives

Food product recalls will be smoother and better protect people and company brands only after food manufacturers link business practices to safety.

Traceability enables far more than recalls.

It provides a great window into manufacturing operations. But traceability can't happen without a foundation of data, which requires digitization and connectivity.

The hurdles on the tech front vary greatly. On one end of the spectrum – say a small, family-owned manufacturing company in a rural area – the barriers to investing in technology might begin with a lack of buy-in, lack of investment capital and its workplace culture. The incentives to change may eventually be a way for the company to stay off the regulatory radar or even survive.

In the middle of the spectrum, a manufacturer might have invested in something that works for now, but they are resource-challenged and lack the time and energy to vet alternatives that work even better and would position the company for growth. They face workforce challenges on the operational side, let alone added expertise in a new specialty. For some of these companies, a recall or scare might prompt a change in the dynamic. This is also why FSMA rules call for implementation of requirements.

At the other end of the spectrum, companies sometimes become complacent, having worked so hard to achieve a certain level of productivity and efficiency. There can be a misguided mindset of “our system is fine,” because it never has been challenged. This is where a continuous improvement mindset is essential. The incentive to progress might be to build market share or become an industry leader.

The Case for Blockchain is Compelling

Blockchain is one of the most promising technological solutions for food traceability because it offers the ability to track in real time – removing the need for time-consuming document processing.

While the system is still only as good as the data that's inputted, blockchain's distributed ledger system removes much of the “human error” that's common in manual traceability systems.

Blockchain has been successfully applied in banking and healthcare and is increasingly being tested by the food industry. As with all technology, however, there are barriers and challenges. Some of these include the cost of implementation, maintenance, and upgrades; infrastructure; access in all locations, such as on-the-high-seas and remote farms; user-friendliness, and access to, availability of, and support for user training. Blockchain will only be as good as the data entered into the system.

Blockchain digitizes secure transactions or “blocks” at every point along the supply chain, viewable directly by those with access to that blockchain ledger, which eliminates the need for intermediaries. Each block is encrypted with a unique, non-manipulable identifier such that blockchain provides a completely decentralized, transparent, and traceable chain of custody.

MEP Tips for Manufacturers

Think about traceability as more than just supplying data for what happens “downstream” in the food system. It also means data on what has happened “upstream.” You will get better information about your supplier and supplies. You will have better information about what happens in your operation.

Traceability provides data that allows you to better forecast production, which leads to more sound budgeting and inventory management. It provides actionable insights into your operation and can link to your financial performance. It always helps companies refine their knowledge of their own operation. They can free up time to do more product research.

Also, with enhanced traceability, you may instantly know that an E. coli outbreak is linked to one of your raw materials. These capabilities go a step further to rapidly identify the source of the material, how much of the affected lot remains, how much was used in production, and exactly where any potentially affected finished products are located.

What's Next

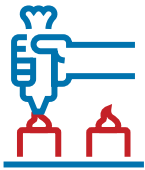
The concepts and vision laid out in the FDA's New Era of Smarter Food Safety blueprint are great. However, many food manufacturers are severely lagging in technology. In order to fulfill this vision, they will need to shift operations to include technologies like computer-driven software, probes, and sensors.

This also applies to the agriculture side. What is the technology needed for farmers to account for bulk items like grain? What can be done to make it easier for farmers to monitor water quality?

The FDA has referred to how other industries track, through digital means, the real-time movement of planes, ride sharing, and packaged goods or how professional services firms are harnessing big data to identify trends. In order to bridge the gap to utilizing artificial intelligence, the Internet of Things, sensor technologies, blockchain, and more, the FDA is encouraging stakeholders to design and execute proof of concept pilots needed for traceability to further scale. This could be testing interoperability and public-private data sharing. The FDA has identified select commodities that have been subject of recent outbreaks, specifically leafy greens, that will be given a high priority.



Pillar 2: Smarter Tools and Approaches for Prevention and Outbreak Response



Overcoming the Stigma of Outbreaks

In order to unite stakeholders, more manufacturers will need to come to the table along with government and academia to discuss prevention, outbreaks and response. A big hurdle has been the stigma associated with outbreaks.

Food manufacturers have been reluctant to be known as an expert in foodborne outbreaks as if it taints their ability to produce safe food. For example, many manufacturers are not aware of the Centers for Disease Control and Prevention's (CDC) Council to Improve Foodborne Outbreak Response (CIFOR), which does tremendous work and has much to offer manufacturers.

A Detailed Roadmap for Tools and Approaches

The FDA outline for this pillar is the most detailed in the blueprint and touches on the vast opportunities, such as:

- Invigorate Root Cause Analyses
- Strengthen Predictive Analytics Capabilities
- Domestic Mutual Reliance
- Inspection, Training, and Compliance Tools
- Outbreak Response
- Recall Modernization

The roadmap speaks to the power of data and the challenges of alignment in communication, standards and processes. As more data streams and tools for rapidly analyzing data become available, collaboration and sharing of information and best practices becomes increasingly important. Manufacturers will benefit from having trusted advisors for these key areas.

MEP Tips for Manufacturers

What works for you is unique to you, and all solutions do not have to be the same. A food manufacturer making pizza is going to have different challenges than one producing condiments, so explore your options with that in mind. This applies with technology as well. If your staff has embraced mobile devices or touch-screen interfaces, don't send them back to the dark ages of using keyboards and computers.

Here is a brief overview of each section of the roadmap to Smarter Tools and Approaches for Prevention and Outbreak Response.

Invigorate Root Cause Analyses: This a huge opportunity for small and medium-sized manufacturers (SMMs), but it will require standardization of protocols and coordination with many stakeholders for it to be most impactful. Concerns include how to be transparent while protecting confidentiality and proprietary interests.

Strengthen Predictive Analytics Capabilities: This includes proof of concept testing for machine learning and artificial intelligence but also how to share information and create a public-private "data trust." It will include factors that impact risk management, such as chemical hazards and environmental conditions.

Domestic Mutual Reliance: This partnership enables FDA and states with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safe national food supply. The challenge is how to effectively collaborate among so many agencies and stakeholders in areas such as sample collection, training and education, and emergency and incident response coordination.

Inspection, Training, and Compliance Tools: Areas of emphasis for operations will include increasing the use of sensor technology and digital reporting on critical control points. Expect to see more access to computer-based and long-distance learning.

Outbreak Response: Efforts will range from coordination of existing data from disparate agencies to enhancing early warning mechanisms and prevention, such as leveraging food testing results to identify possible outbreaks.

Recall Modernization: The blueprint accounts for simplifying and expanding communication mechanisms to prevent consumers from buying recalled food products.

What's Next

As food safety culture evolves, manufacturers will face even more choices about how to engage with trade organizations. Which trade groups are going to be most beneficial? How much are financial commitments? But tapping into that expertise is valuable for resource-challenged manufacturers on so many fronts.

During the pandemic, the FDA conducted remote inspections of certain food importers and state/local inspection agencies utilized remote tools to evaluate domestic food sites. These successes will lead to domestic proof of concept testing for virtual audits, remote inspections and component inspections.

Pillar 3: New Business Models and Retail Modernization



Heightened Awareness of Allergens and Marketing Tactics

This pillar may not impact as many food manufacturers as much as the others, but it has risen to the fore in a big way for many.

Many manufacturers have learned the hard way that precision matters in retail marketing in order to be compliant with various regulators. Federal regulators have been closely monitoring the grocery aisle for any product advertising unsubstantiated health or disease-prevention benefits. The highest profile example was POM Wonderful LLC losing a five-year regulatory and legal battle over claims of health benefits in its line of pomegranate juices and supplements. The lesson is clear: there are rules to follow about scientifically substantiating claims if you want to tout the health benefits of your product.

The president of the United States signed the Food Allergy Safety, Treatment, Education, and Research Act of 2021 or the FASTER Act into law in April 2021. It updates food allergy laws to include sesame seeds as a ninth food allergen, which impacts product labeling and marketing claims. Many food manufacturers use sesame seeds, and sesame seed paste, as an ingredient, and they will soon be required to list them as allergens in the labeling.

The heightened societal awareness of allergens led some food manufacturers to claim their products were allergen free, only to learn their suppliers used allergens in their ingredients. Being allergen-free is a big deal for many consumers, and some manufacturers unknowingly made claims that they could not support or turned out to be false. Some were able to backpedal from marketing claims and revise package labels, but others have had to revise production processes.

Claiming a food product is manufactured in an allergen-free environment also means that product is not indirectly exposed to allergens.

For such a claim to be true, workers could not bring peanuts, peanut butter or other peanut products into a break room at their facility.



MEP Tips for Manufacturers

Have more than one supplier for key ingredients. This redundancy is a good business practice and becomes even more valuable in the event of an outbreak or disruption.

Increase your direct communication with your suppliers. Understand their ingredients and processes. Have specified, detailed contracts with suppliers, delivery carriers, and customers of products to state who does what and what specs need to be met during transportation. As traceability improves and more data is available, collaborating with your suppliers could lead to efficiencies, savings and more opportunities for product development.

'Last Mile' Liability for Food Delivery

The growth in food delivery apps, ghost kitchens and new business models pose interesting questions about liability and risk prevention. Who owns the last mile of delivery in the event of an outbreak? In most e-commerce delivery, carriers such as FedEx and UPS are not considered liable. In that case, food delivery liability may reside with whomever packaged the product. The potential of cross contamination could be a concern for retail businesses.

According to the CDC, restaurants and other retail establishments remain the most common nexus of foodborne illness outbreaks, which could explain the reduction in foodborne outbreaks during the pandemic. The retail modernization focus remains on known risk factors to change behaviors and practices. Generally speaking, restaurants also lack the technology and skill sets to ensure adequate risk prevention and traceability to deal with an outbreak, and postal services are not focused on maintaining the cold chain of perishable products.

What's Next

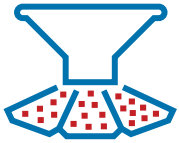
The impetus is now on manufacturers to know more about their suppliers and the subcomponents of their ingredients. This has not been a strong suit for many, especially with impacts from the COVID-19 pandemic that prevented on-site visits and led to supply chain disruptions.

The arrival of omnichannel food distribution and new business models, which covers a range of online, mobile device, telephone shopping platforms in addition to brick-and-mortar stores, will heighten the need for adequate time and temperature measurements. There also will be a focus on packaging to reduce the possibility of cross contamination for delivery operations.

Novel ingredients such as meatless proteins, a trend toward clean labeling, and new production systems present challenges, and opportunities. The capability already exists for predictive analytics but as mentioned, the collection of adequate data lags throughout the food supply chain.

The FASTER Act also will present opportunities on the research side. It requires the federal government to analyze the most promising research opportunities to help scientists develop more effective treatments and, hopefully, a cure for food allergies.

Pillar 4: Food Safety Culture



How Safety is Good for Business

In many ways, food manufacturers have already proven that a robust food safety culture is good for business. The common characteristics of a manufacturer with a solid food safety culture in place align with those for operational safety and preventive controls, lean manufacturing and even employee wellness. Those characteristics include:

- Sufficient staff and infrastructure in place to ensure compliance.
- Effective behaviors are celebrated, built into recognition and even compensation.
- Lines of communication are open throughout the company.
- Immediate action is valued.
- These initiatives are led by top management.

This holistic approach values food safety as a foundational element. While it is not negotiable, it does not prevent the manufacturer from investing in:

- Productivity improvement
- Cybersecurity
- Inventory control
- Automation
- Supply chain resiliency

A successful food safety culture extends beyond regulatory areas.

For example, third-party qualifications are increasingly seen as a competitive advantage and required to do business with the largest food and beverage companies.



MEP Tips for Manufacturers

Tap into expertise to learn how others have successfully implemented a food safety culture. Attend webinars, read white papers, and reach out to trade organizations. View this as you would a continuous improvement process for operations.

One of the best ways to build cross-departmental alignment on any workplace cultural issue is to begin with a small cross-departmental team. The people on your front lines are a great resource for developing a food safety culture.

Hurdles Remain for Many

Many food manufacturers, however, have not bought into how food safety relates to good business practices. They may have separate organizational structures for people in operations and safety.

One of the symptoms of this is when a manufacturer views equipment maintenance as a cost of doing business but would never halt production for the time needed to implement safety procedures or training. Preventative activities aren't seen as a profit center and dismissed as unimportant.

Another psychological hurdle is it is hard for many people to see something is working when it results in the absence of something else. This can be true for efforts to reduce workplace injuries, scrapped material in operations, or preventing contaminated product. It's often a matter of using data to turn assumptions into knowledge.



Third-party Certifications Drive Improvements

An increasing number of food companies are requiring suppliers to have third-party food safety audits, and the FDA has recognized these audits as one way to satisfy FSMA supply chain preventive controls. They've become extremely common across the globe and are thought to be a means of increasing market share, improving process controls, and driving continuous improvements.

They are typically conducted by independent, auditing companies who employ experts to objectively evaluate the food safety systems of food and beverage manufacturers. These auditors highlight nonconformances and areas that need improvement and help manufacturers improve their systems and reach a better level of compliance.

While these auditing standard holders aren't affiliated with government agencies, their requirements often draw strong parallels and can greatly help a plant achieve compliance with government regulations. It's worth noting that audits are only as good as the auditor.

Many of these audits are benchmarked to the Global Food Safety Initiative (GFSI), an industry-driven initiative for the development of food safety management systems to ensure food facilities are processing safe food for consumers. The standard holders (SFQ, BRC, FSSC 22000, etc.) have created audits to satisfy this GFSI certification. This organization consistently revises their standard to make improvements and reflect advances in technology, emerging hazards, and other changes to the industry.

They also have strict parameters around auditor competency and audit format to keep these audits robust and consistent, no matter where in the world the plant is located. These GFSI-benchmarked audits are largely respected and globally accepted by the largest food companies. High scores and continued certification solidifies a company's reputation as a consistent provider of safe, high quality products; both of which are highly desired by customers.

Gaining high scores and audit certifications is a great way for a manufacturer to differentiate themselves from competitors and leverage food safety as a competitive advantage.

It elevates the importance of a good food safety culture, is a driver for continuous improvement, and protects brand trust.

What's Next

The FDA blueprint states that the industry will not make dramatic improvements in reducing the burden of foodborne disease without doing more to influence the beliefs, attitudes, and, most importantly, the behaviors of people and the actions of organizations. They suggest considering how companies' positive food safety culture can factor into reduced inspection frequencies, which provides an additional incentive for SMMs.

The FDA recently released the proposed rule, "Requirements for Additional Traceability Records for Certain Foods," a key component of their New Era of Smarter Food Safety blueprint and FSMA (section 204d). They intend to publish the final rule in 2022, and manufacturers will need to work toward compliance by strengthening their traceability systems.

As more manufacturers embrace a food safety culture, there will be more involvement with trade organizations, suppliers, and regulatory agencies. There will be more integrated teams at the industry level and at the company level. Largely this effort becomes education and awareness, promoting a food safety culture from farms to manufacturers, restaurants, last-mile delivery and consumers.



The Greater Regulatory Landscape



Food Manufacturers Face a Myriad of Compliance Issues

The food processing regulatory landscape is increasingly complex. The Food Safety Modernization Act (FSMA) of 2011 is the landmark law that enables the FDA and food manufacturers to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. But it is not the only regulatory concern for food manufacturers.

More than a dozen federal agencies administer laws related to food safety, though the FDA and USDA's Food Safety and Inspection Service (FSIS) get the majority of government funding and staffing.

Food manufacturers face compliance requirements from agencies as diverse as:

- OSHA, a federal agency that deals with worker and equipment safety issues.
- EPA, which regulates emissions common in most manufacturing.
- State agriculture and public health departments.
- Local health and local jurisdiction authorities, which account for zoning and other matters. This frequently is done by county or city but also includes special service districts.
- Cottage food laws in many states that allow small-scale production in homes that do not have commercial kitchens.

FSMA provides the FDA with enforcement authorities designed to achieve higher rates of compliance with prevention – and risk-based food safety standards. The law also holds imported foods to the same standards as domestic foods.



What's Next

In addition to future activities around the New Era of Smarter Food Safety, the FDA will continue to expand enforcement activities around the FSMA rules. Prior to the pandemic, there was much focus on the Preventive Controls for Human and Animal Food, but we'll see that focus continue to expand to the other rules, such as the Intentional Adulteration (IA) rule and the Foreign Supplier Verification Program (FSVP).

The FDA has stated a desire to expand use of whole genome sequencing to move faster on outbreaks, especially around produce and the interaction between animal operations and produce operations and for food importers.

As we return to normal, you can expect all governmental agencies to renew their enforcement efforts and release new regulations from initiatives that were previously stalled by the pandemic.

MEP Tips for Manufacturers

Don't go it alone. The MEP National Network offers a full range of food safety and quality services specific to food manufacturing and can help you with any compliance issue. Other services include on-site training and employee development.

Experts at your local MEP Center provide services that range from technical project assistance to developing and implementing an effective food safety and quality system enabling operational efficiencies and continuous improvement in your facilities.

Contact your local MEP Center



The MEP National Network is a unique public-private partnership that delivers comprehensive, proven solutions to U.S. manufacturers, fueling growth and advancing U.S. manufacturing.

Focused on helping small and medium-sized manufacturers generate business results and thrive in today's technology-driven economy, the MEP National Network comprises the National Institute of Standards and Technology's Manufacturing Extension Partnership (NIST MEP) and 51 MEP Centers located in all 50 states and Puerto Rico.



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