

Serving Up Facility Design and Construction Considerations to Outsmart Food Recalls

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Revised safety standards, smarter traceability and inspection tools, and forward-thinking facility design are empowering manufacturers to strengthen every stage of the production process, from ingredient sourcing to final product distribution.



More than a century ago, food safety was a public health disaster. Contaminated food, milk and water caused typhoid fever, tuberculosis, botulism and scarlet fever, with typhoid alone affecting 100 per 100,000 people in 1900. Food producers relied on ice blocks and other primitive cooling methods to preserve products, while milk was distributed unpasteurized. It took Upton Sinclair's meatpacking exposé, *The Jungle*, to spark the first food safety laws in 1906.

While progress has certainly been made, today there are roughly 500 food recalls annually, indicating there is still much work to do. Despite food safety advancements, the food industry continues to face significant challenges in achieving safety across the food supply chain.

When it was signed into law in January 2011, the Food Safety Modernization Act (FSMA) marked the most comprehensive overhaul of U.S. food safety regulations in more than 70 years. FSMA gave the Food and Drug Administration (FDA) its broadest new authority since the Federal Food, Drug and Cosmetic Act of 1938, shifting the focus of food safety from responding to contamination to preventing

it. Other food safety milestones are included in the chart below. (See Figure 1.)

Recent Food Safety Regulation Changes

The shifts in food safety regulations have reshaped the expectations placed on manufacturers, requiring a proactive approach to managing risks and product traceability. Regulatory authorities are raising the bar, driving the industry to adopt smarter, more integrated safety practices. A wave of FDA regulatory updates is accelerating the manufacturing industry's food safety transformation.

- **FDA's 2024 Appendix 1 revision introduces a risk-based framework.** The updated guidance shifts from prescriptive hazard lists to facility-specific risk assessments, requiring manufacturers to conduct thorough hazard analyses tailored to their operations and processes rather than following standardized controls. Previously standardized process hazards have been removed from FDA tables and must now be evaluated individually by each facility, placing greater responsibility on food producers to determine significant hazards within their unique operational contexts.

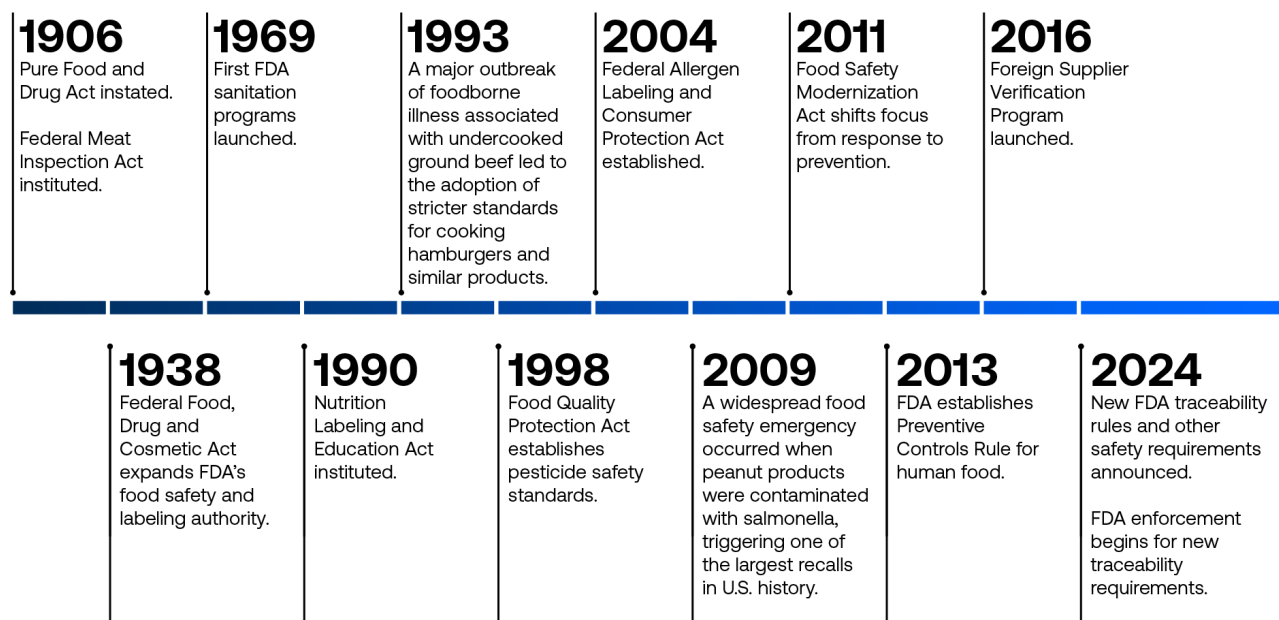


Figure 1: Food safety timeline. FDA moves toward a more proactive approach when it comes to food safety standards, rules and regulations.

- **FSMA's Section 204 mandates enhanced traceability requirements.** Manufacturers handling foods on the FDA's Food Traceability List must capture and maintain key data elements at every crucial tracking event, including in the receiving, transformation and shipping phases.
- **Required 24-hour data retrieval.** All traceability records must be accessible within 24 hours of an FDA request, driving widespread investment in digital systems and automated data capture technologies throughout the industry.
- **Evolving compliance supported by facility design.** To meet both current and future regulatory demands, new facilities require adaptable infrastructure that accommodates changing hazard identification frameworks, environmental monitoring systems and rapid response capabilities.
- **Mandatory integration of digital infrastructure.** IoT devices, RFID scanners and barcode readers are now essential facility features, enabling real-time data capture and reducing human error in compliance documentation and traceability record-keeping.

Recall Readiness: From Prevention to Reaction

Recalls are among the most disruptive and costly challenges in food manufacturing. Industry leaders view both recalls and near-miss events as critical opportunities for improvement.

Rather than stopping at identifying the failure point, root cause analysis digs deeper to uncover systemic issues, such as gaps in training, sanitation or supplier oversight. The insights gained are used to revise hazard plans, refine production workflows and retrain staff, often resulting in internal standards that exceed regulatory requirements.

While regulatory frameworks have improved traceability, the real test of a food safety system lies in recall management, both the preventive measures and how quickly and effectively a company can respond when contamination occurs.

Modern recall effectiveness depends heavily on integrated digital traceability systems, linking warehouse management systems, manufacturing execution systems, IoT sensors and enterprise resource planning (ERP) databases into a unified data flow. This allows real-time tracking from receipt of raw materials to product distribution, enabling precise, targeted recalls that reduce scope, cost and brand damage. Many manufacturers are also adopting global data standards such as a GS1 digital link to allow interoperability across suppliers and international markets.

With changing consumer preferences as well as other external factors, modern facilities are transforming to meet current challenges. Key factors tied to recall management include:

- **Segregated zones.** These are essential for separating raw materials from ready-to-eat products, reducing the risk of cross-contamination. These zones are often physically divided by walls, air locks or sanitation stations to preserve strict hygiene boundaries.
- **Controlled traffic patterns.** These help direct personnel, equipment and materials through facilities in ways that prevent the introduction of contaminants. Measures include: designated pathways, restricted access points and directional flow systems that separate clean and dirty operations. Simplicity is crucial. Keeping control processes intuitive promotes compliance, while complex processes can lead to shortcuts and nonadherence.

- **Environmental monitoring systems.** These provide continuous oversight of critical conditions such as temperature, humidity and microbial presence. These systems enable early detection of potential hazards and support timely corrective actions before contamination can spread.

Continuous environmental pathogen monitoring, strategically placed microbial sensors, automated air sampling and real-time cloud reporting is becoming standard for high-risk areas. For ready-to-eat products, many facilities employ a hold-and-release protocol, withholding distribution of finished lots until pathogen testing confirms safety. This approach, when automated, allows both rapid clearance of safe product and containment of contaminated batches.

Despite ideal efforts, even when using advanced preventive food safety measures, contamination and recalls can still happen. That is where reaction protocols come into play.

The core of recall response lies in lot tracking and traceability. Manufacturers aim to limit the size of production lots so that in the event of contamination only a small, well-defined batch needs to be pulled. Automation has made this more precise. Sensors and digital systems now collect detailed data throughout the production process, allowing manufacturers to pinpoint the exact time and location of a contamination event. This data-driven approach not only speeds up the recall process but also reduces its scope and cost.

When a recall is triggered, manufacturers must act fast. It is important to identify the affected lot, trace its distribution and initiate a root cause analysis. This investigation can take months and often leads to new internal standards that exceed regulatory requirements. In all sectors of the food industry, manufacturers are often ahead of regulators, using lessons from past recalls to drive continuous improvement.

Ultimately, the goal is not just to react to recalls but to design systems that make them less likely and less damaging. From X-ray inspections and AI-driven defect detection to supplier audits, customer-driven quality demands and changing regulations, the industry is moving toward a more resilient, data-informed, traceability-centric model of food safety.

The Role of Automation in Facility Design

Automation and artificial intelligence are playing an increasingly important role in addressing food safety challenges. Automated systems now monitor temperature, humidity and other crucial parameters in real time, enabling faster responses to deviations. AI-driven feedback loops allow equipment to self-correct based on historical performance data, which improves consistency and reduces the risk of contamination.

Additionally, in the realm of automation, X-ray inspection technology has become an essential tool in product integrity. The integration of X-ray inspections into quality control processes reflects a proactive approach to food safety, emphasizing prevention over reaction. These systems can detect physical contaminants such

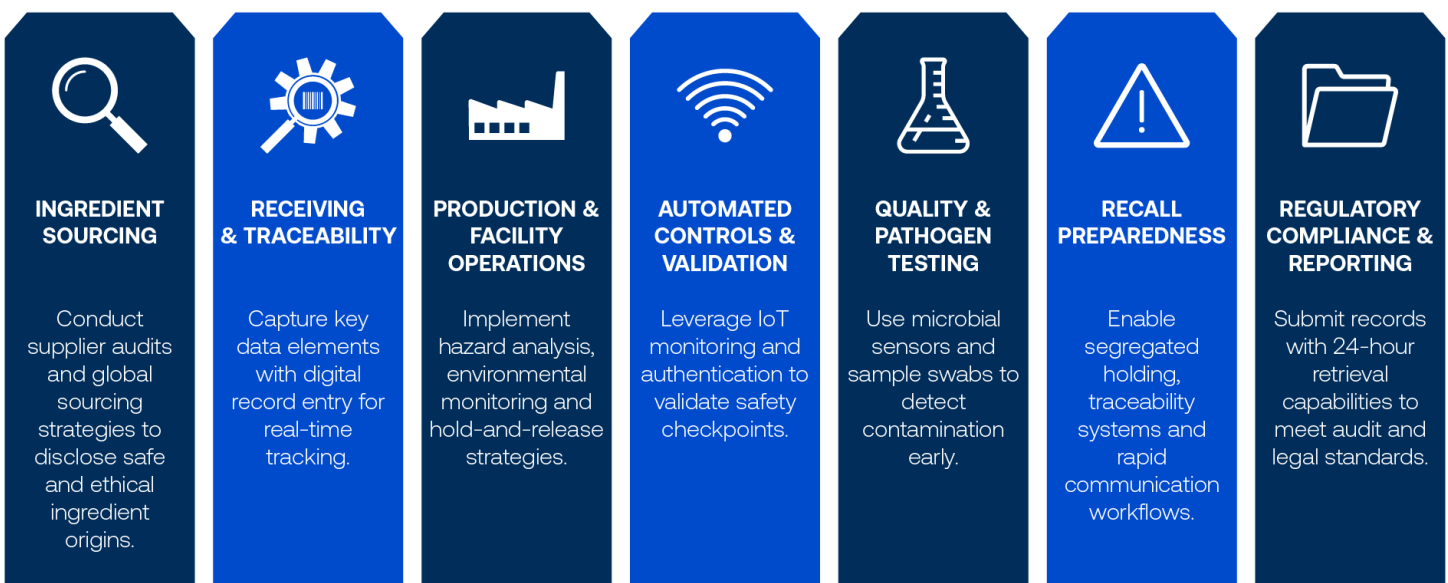


Figure 2: These seven pillars of food safety compliance illustrate the progression of modern food safety compliance from sourcing to reporting.

as metal, glass, bone and certain plastics that may be missed by traditional inspection methods. By scanning products in real time, X-ray machines help manufacturers identify and remove potentially hazardous items before they can reach consumers.

Beyond contaminant detection, automation now supports regulatory validation by generating complete, time-stamped audit trails for every production step. As more food safety systems connect to the cloud, cybersecurity safeguards, such as encrypted data transmission, controlled network access and multi-factor authentication, are essential to protect sensitive traceability and recipe data from tampering or loss.

Food Safety Trends: A Look Ahead

While automation is helping transform the industry, facility design is evolving in parallel. Architects and engineers are prioritizing and refining hygienic zoning, controlled airflow and sanitation-friendly materials. HVAC systems, drainage design and lighting are being optimized to support environmental monitoring and pathogen control. Dedicated training rooms, secure server spaces and ADA-compliant access points are being integrated to support compliance and operational efficiency.

Supply chain oversight has also intensified. Manufacturers now treat co-manufacturers and ingredient suppliers as integral to their own operations, applying the same hazard analyses, process controls and recall protocols. Onboarding often includes supplier audits, document verification and periodic production testing. Retail partners increasingly require Global Food Safety Initiative, Safe Quality Food or British Retail Consortium certifications and may impose stricter allergen controls and recall readiness benchmarks than regulatory minimums.

As the food industry adapts to the demands of FSMA's Section 204 and the revised Appendix 1, it is clear that food safety is no longer just a static checklist. It is a dynamic, integrated system that spans design, operations and supply chain management.

Creating robust food safety measures are critical and future trends will likely address key concerns such as:

- **Global sourcing complexity.** Ingredients often pass through multiple countries and handlers before reaching the production floor, making it difficult to uphold consistent safety standards. This complexity is compounded by the variability in international regulations and the limited interoperability of digital systems across organizations. Any measures that can uphold consistent safety standards should be prioritized.
- **Pathogen control.** Environmental monitoring and sanitation must be rigorous and continuous for ready-to-eat and perishable products. Facilities are incorporating more accessible sampling points, enhanced lighting and designated

areas for swabbing and testing. Sanitation protocols will continue to be stringent with the increased use of captive uniforms, footwear and segregated zones to prevent cross-contamination.

- **Recall preparedness.** While traceability systems have improved, many manufacturers still struggle with executing rapid, targeted recalls. Inadequate lot tracking or delayed test results can expand the scope and impact of recalls. Facilities are now being built with recall scenarios in mind, incorporating segregated holding areas, clear labeling systems and centralized communication hubs to support swift response.
- **Sustainable design and building systems.** Resilient facility design incorporates sustainability without compromising safety. This includes selecting materials with low embodied carbon that can withstand rigorous sanitation, integrating energy recovery in HVAC systems without introducing microbial risk and designing for modular adaptability for future regulations or technologies.
- **Safe and durable materials.** While stainless steel remains the industry standard for durable materials, sustainable alternatives are emerging that offer reduced environmental impact and enhanced end-of-life recyclability. Recycled aluminum composite panels and bio-based polymer surfaces are gaining momentum as viable options. Additionally, seamless flooring solutions such as epoxy terrazzo and polished concrete are becoming increasingly popular for their combination of hygiene benefits and aesthetic appeal.
- **Supplier and co-manufacturer compliance.** Manufacturers are increasingly treating co-manufacturers as extensions of their own operations, requiring them to adhere to the same food safety plans, control points and audit procedures. Supplier relationships are managed through a combination of documentation, on-site audits and periodic validation testing. Retailers, too, are exerting pressure on co-manufacturers to meet higher standards, often requiring additional inspection steps.
- **Cost of compliance.** Implementing traceability systems, upgrading facilities and maintaining rigorous training programs require substantial investment. While larger manufacturers may have the resources to lead the way, others may struggle to keep pace without phased implementation strategies or external support.
- **Data management.** While FSMA's Section 204 requires rapid access to traceability data, many facilities still rely on fragmented or outdated systems. Integrating ERP databases, warehouse management systems and traceability platforms across diverse suppliers remains a major challenge, particularly for small and midsize manufacturers. Efforts to improve data management systems will move the industry forward.

- **Workforce training and retention.** Food safety protocols are only as effective as the people who implement them. High turnover rates in manufacturing environments can undermine even the most ideal food safety measures. Facility owners must invest in continuous training programs, often delivered through on-floor kiosks or digital learning platforms to help staff remain informed and compliant.

A significant amount of thought should go into creating a streamlined food safety system. By embracing traceability, automation and collaborative, sustainable design, manufacturers can position themselves to meet regulatory requirements while fostering safer, more resilient operations. The path forward demands investment, innovation and a culture of continuous improvement, so that manufacturers are not only regulatory compliant but also resilient, adaptive and ready for the food safety challenges of the future.

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