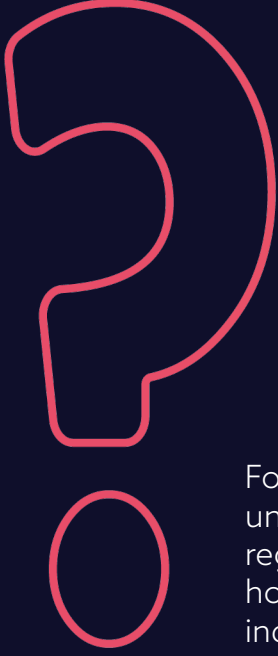# FSMA 204

FREQUENTLY ASKED QUESTIONS

Section 204 of the Food Safety and Modernization Act (FSMA) marks an unprecedented step in food safety regulation, mandating more comprehensive traceability requirements than ever before. Designed to protect public health by enhancing the ability to track high-risk foods across the supply chain, FSMA 204 aims to prevent and respond swiftly to contamination outbreaks.

For food safety and quality professionals, understanding and preparing for this regulation is critical, as it will shape how traceability is managed across the industry. Staying informed about the Food Traceability Final Rule and implementing the right systems now can protect your brand, ensure compliance, and support safer, more transparent food systems for the future.

TRACEGAINS

1 WHAT IS FSMA 204?

FSMA 204 is a final rule under the Food Safety Modernization Act (FSMA) requiring additional traceability records for certain high-risk foods. The rule aims to improve food safety by enhancing the Food and Drug Administration's (FDA) ability to trace the origins of contaminated food during outbreaks and recall events.

2 WHEN DOES FSMA 204 GO INTO EFFECT?

While FSMA 204 is already law, the rule's enforcement is set to begin January 20, 2026. This period gives food and beverage companies time to implement the necessary traceability systems and processes to ensure compliance.

3 WHO IS AFFECTED BY FSMA 204?

FSMA 204 applies to companies handling certain foods that are considered high-risk, including but not limited to dairy products, fresh produce, nut butters, and ready-to-eat deli salads. However, many retailers may require their entire supply chain to comply, even if not all foods fall under the rule.

4 WHAT ARE THE KEY REQUIREMENTS OF FSMA 204?

The rule mandates that companies keep additional traceability records for certain foods, such as:

- **The Key Data Elements (KDEs):** Specific information that must be recorded at critical tracking events (e.g., growing, shipping, receiving).
- **Critical Tracking Events (CTEs):** Key points in the food production and distribution process where data must be captured (e.g., harvesting, packing, processing, and shipping).

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HOW DOES FSMA 204 IMPACT FOOD QUALITY & SAFETY PROFESSIONALS?

Those in food safety and quality roles will play a crucial role in ensuring compliance by:

- Implementing new record-keeping systems to capture required KDEs at CTEs.
- Collaborating with suppliers to ensure traceability records are complete and accurate.
- Ensuring that internal processes are updated to meet FSMA 204 standards.

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WHAT SHOULD I DO TO PREPARE?

- **Take advantage of available resources:** Multiple resources are available to help organizations navigate compliance, including guidance and assistance available directly from the FDA. Consultative resources also exist to help brands create a workable path to full compliance.
- **Evaluate your current traceability system:** Assess if your existing traceability records cover the KDEs required by FSMA 204.
- **Collaborate with suppliers:** Work closely with your suppliers to align on data sharing and record-keeping for KDEs and CTEs.
- **Implement a digital traceability tool:** Use networked solutions like TraceGains Supplier Management for enhanced collaboration and Supplier Compliance for automated capture and storage of incoming KDEs, allowing visibility into your supply chain.

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WHAT ARE THE CONSEQUENCES OF NONCOMPLIANCE?

Failure to comply with FSMA 204 can lead to FDA enforcement actions, including fines, food recalls, and damaged business reputations. Being proactive in implementing traceability systems will help mitigate these risks.

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HOW CAN I STAY UPDATED ON FSMA 204 & OTHER GLOBAL REGULATIONS?

Staying current with evolving regulations is essential for maintaining compliance and managing risks. TraceGains' **Regulatory Global** solution, powered by SGS Digicomply—the world's leading source for global intelligence data—provides an unparalleled resource for accessing up-to-date regulatory data and safety alerts across the globe. This powerful tool ensures your team has the latest insights, helping you respond proactively to shifting compliance landscapes worldwide.

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HOW CAN A TOOL LIKE TRACEGAINS HELP?

TraceGains and **iFoodDS** provide secure solutions for capturing your complete supply chain, as well as building the secure data flows required to meet and exceed FSMA 204 compliance requirements. TraceGains offers supplier document and data collection, scorecarding and data-sharing capabilities that streamline and accelerate supplier collaboration. iFoodDS, founded by food industry regulatory experts, provides tools and guidance for organizing traceability data and building processes and programs around solid compliance. Together, TraceGains and iFoodDS combine ingredient and supplier data with network intelligence and expert guidance to help businesses fast track compliance, while gaining unique business insights.

For more information on FSMA 204 and how TraceGains can help, request a demo

TraceGains is reshaping the CPG supply chain through a networked ingredients marketplace, making it easy to share documents and data while streamlining operations. With connections to over 85,000 global locations, we help brands boost agility, strengthen resilience, and promote sustainability across the supply chain.