KEZZLER

e-Book

From compliance to opportunity: FSMA 204

A practical guide to traceability requirements, implementation, and the opportunities beyond compliance.



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Achieve FSMA 204 compliance with advanced traceability

The Food Safety Modernization Act (FSMA) 204 requires certain food businesses to trace high-risk foods through the supply chain and report that data to the **Food and Drug Administration** (FDA) on request. Getting compliant doesn't mean reinventing your operations. The right traceability approach gets you there efficiently and gives you clearer visibility into your supply chain in the process.

We help companies meet this requirement without a system overhaul. Before we look at how, let's cover what the regulation actually requires, the pitfalls that catch most businesses off guard, and what it means for you.

Everything you need to know about the traceability rule

Despite regulations and technological advances, the global food supply chain still faces challenges. Issues like contaminated foods, counterfeit foods, and opaque supply chains can all compromise food safety.

In the United States, increased transparency is essential to meet consumer expectations and regulatory demands, which is where the FSMA comes in. Introduced in 2011 by the US government, FSMA marked a significant shift in food safety regulation by increasing oversight and enforcement of food safety practices.

In 2023, FSMA was expanded to include the Food Traceability Rule, or FSMA 204, which emphasizes enhanced record keeping requirements for entities who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). This rule drives the digitization of the food supply chain, making it crucial in today's evolving food industry. FSMA 204 highlights the need for a comprehensive traceability system to better protect consumers from foodborne illnesses. The goal is to adopt a smarter, digital- first approach for the rapid identification of contaminated foods from source to distribution.

In August 2025, the FDA proposed a 30-month extension to the compliance deadline, moving the enforcement target to July 2028. This extension recognizes the immense operational challenges facing the industry, providing critical time to develop adequate IT frameworks, uplift less data-ready supply network partners, and implement the necessary digital infrastructure for data aggregation and supply chain interoperability.

The FSMA 204 timeline

2011 — FSMA introduced

The US government introduces the Food Safety Modernization Act (FSMA). This marks a significant shift in food safety regulation by increasing oversight and enforcement of food safety practices.

2023 — Expansion to FSMA 204

FSMA expands to include the Food Traceability Rule (FSMA 204). This rule emphasizes enhanced traceability and drives the digitization of the food supply chain to protect consumers from foodborne illnesses.

2025 August — Deadline extension

The FDA proposes a 30-month extension to the compliance deadline. This extension acknowledges the operational challenges companies face, providing time to build IT frameworks, support less data-ready partners, and establish digital infrastructure.

2028 July 20 — New enforcement date

If your products contain any ingredient on the FTL, you need full tracing and reporting capability in place by July 20, 2028. Starting that date, the FDA can request your records at any time, and you're required to deliver them.

The building blocks of FSMA 204

Meeting FSMA 204 comes down to two things: capturing the right data, and capturing it at the right moments in your supply chain. Get either one wrong, and you won't be able to produce a complete record when requested.

If you're making operational decisions, you need information on things like batch numbers, time picked or packed, and shipping and receiving information — this is where Key Data Elements (KDEs) come in. KDEs are critical pieces of information attached to products, helping to piece together what's happening with products in a supply chain.

Critical Tracking Events (CTEs) record key steps in the supply chain where products are altered (e.g., packed or processed), thus are vital for effective tracing and compliance. CTEs record what happened and when, from harvesting or production through processing, distribution, and receipt.

KDEs and CTEs must be connected to a Traceability Lot Code (TLC), ensuring they are readily accessible when that TLC is queried.

As such, KDEs vary depending on the commodity tracked and the specific CTE involved.

There are seven different CTEs for food supply chains:

01 Harvesting

02 Cooling before initial packing

03 Initial packing of produce or aquaculture food

04 First land-based receiver for food obtained from a fishing vessel

05 Shipping

06 Receiving

07 Transformation

Let's dive even deeper with examples to see how this works in practice.



Shipping and receiving as CTE examples

Shipping and receiving are CTEs that involve the physical relocation of products. Each must include specific KDEs to ensure traceability. These two CTEs are similar as they both involve the product changing physical location. They must include information on when and where shipping began or was received, involving external parties and intracompany transfer registrations (excluding intralocation transfers).

Shipping KDEs

- → Assigned TLC
- → Amount and measurement unit of the food
- → Description of the food product
- → Location description of the immediate subsequent recipient (other than a transporter)
- → Location description of the location from which you shipped the food
- → Date of shipment
- → Description of the source of the traceability lot code or its reference
- → Reference document type and reference document number

Receiving KDEs

- → Assigned TLC
- → Amount and measurement unit of the food
- → Description of the food product
- → Location description of the immediate previous source (other than a transporter)
- → Location description of where the food was received
- → Date of receipt
- → Description of the source of the traceability lot code or its reference
- → Reference document type and reference document number



What foods are subject to the FSMA 204 rule?

The FSMA 204 FTL designates the initial foods subject to additional traceability record keeping requirements. The extensive list can be found on the FDA's website and will evolve over time.



Cheeses



Shell eggs



Nut butters



Leafy greens



Tomatoes



Tropical fruits



Finfish



Crustaceans



Mollusks

FSMA 204 traceability challenges



Variety of product data across SKUs

Managing different KDE requirements for a wide range of products (often within the same company) necessitates flexible metadata systems to accommodate each SKU's unique needs.



Data acquisition from traditionally data-poor environments

Growers face significant challenges related to costs, technical complexities, and infrastructure. FSMA 204 requires data acquisition from these growers, who are often in data-poor and digitally immature environments, making initial KDE collection difficult.



Fragmented systems and data silos

Data required by FSMA 204 is often spread across multiple systems that don't communicate with each other — no one system has all the data needed for compliance. This necessitates a unified traceability layer to create a cohesive framework, ensuring compliance and data accessibility.



Trade network data interoperability

Achieving system interoperability is crucial as FSMA 204 mandates information sharing across trading partners, but many systems are incompatible and unable to communicate effectively.



Exponential increase in data points

Linking diverse SKUs and widespread distribution channels leads to a rapid increase in data points — often millions — necessitating robust systems to manage and link these points for accurate traceability.



24-hour data collation deadline

Information must be rapidly compiled and submitted electronically to the FDA upon request. Considering data fragmentation and the large volume of unique data points across many SKUs, meeting this 24-hour deadline is challenging for any organization under current systems.

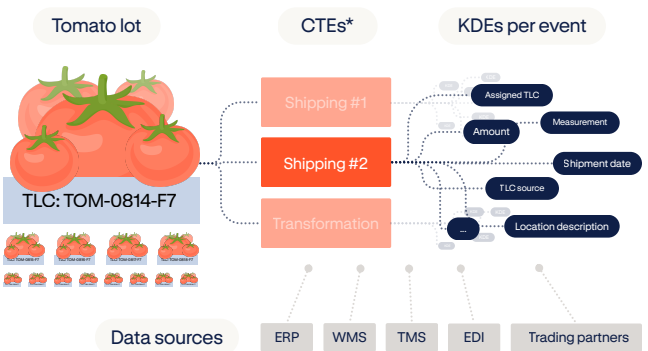


Addressing exponential growth of data points

Due to the expansive nature of FSMA 204, record requests can be broad and encompass multiple lot codes without a predefined limit. This complexity arises from the diverse sources and formats of traceability records, often stored across disparate systems.

Coordinating data from various stages of production and shipment — which lack centralization — therefore poses a significant compliance challenge.

A single inquiry can span several lot codes. Handling, modifying, and shipping listed food items can generate numerous data points for each lot code. With multiple lot codes in play, aligning responses to a single request could require managing thousands of unique data elements, all of which need to be efficiently orchestrated.



**Applicable CTEs and KDEs depend on the product and supply-chain activity.*

Implementing integrated traceability systems and advanced data management tools can streamline this process, ensuring compliance and efficiency. A key element in managing this complexity is understanding and utilizing TLCs, which we'll cover next.

What are TLCs, and are they crucial?

TLCs are essential for FSMA 204 compliance and ensuring the integrity of the entire supply chain. Each TLC is a sufficiently unique identifier and the anchoring element of a digital thread that details a product's journey from production to distribution and sale.

A TLC is typically created at three specific supply chain events: when a raw food is initially packed, when seafood is first received on land, or when ingredients are transformed.

TLCs trace three key aspects of a product:

The place where the TLC was applied to the product which allows rapid tracking back to the source.

The batch, lot or item number of the product which identifies a single product or a group of products.

KDEs attached to the product specified within FSMA 204 for a particular CTE.

Once assigned, a TLC must be maintained as the product moves downstream through distributors, warehouses, retail food establishments or grocers, unless a new transformation takes place or a kill step is applied



How to create your TLCs

Creating TLCs depends on what works best for your operation — this, inherently, is the beauty of TLCs.

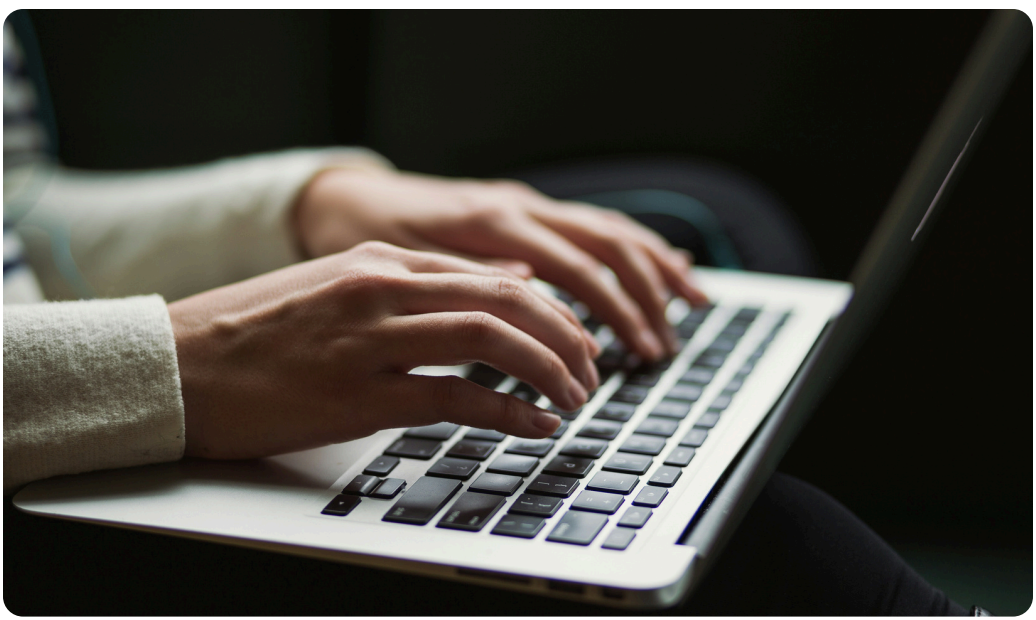
FSMA 204 doesn't require TLCs to be globally unique or encoded into machine-readable data carriers. The rule specifies that TLCs must be "sufficiently unique" for traceability purposes, giving you significant leeway in how you structure them.

You can choose from several TLC constructs based on your operation's context:

01 A randomized alphanumeric string

02 A Global Trade Item Number (GTIN) combined with other relevant Application Identifiers (AIs). For example, a batch ID/lot (forming LGTIN) or a GTIN in combination with the product's expiration date.

03 Any combination of elements, such as a code identifying the manufacturer plus a Julian date or different combinations of similar elements, as long as it provides a "sufficiently unique" identification capability.



Granularity boosts resolution

The flexibility of TLCs allows you to control their granularity — whether per batch or individual item — depending on your traceability needs.

Let's look at three levels of granularity:

Lot level*

→ All products share roughly the same attributes, inheriting the same TLC.

*Note: Lot-level TLCs may not meet the "sufficiently unique" threshold required by FSMA 204.

Batch level

→ Groups of products share a similar attribute (e.g. time of production).

→ The attached TLC changes when the attribute changes.

Item level

→ Each individual product has its own TLC, providing the highest level of granularity.

In general, the more granular your TLC system (toward "item level"), the more benefits you gain. Increased granularity allows for more precise recalls, targeting specific products rather than broad recalls of entire batches or lots.

Swift responses boost safety

Together, these key identifiers of a product enable granular traceability, pivotal for meeting requirements and safeguarding public health.

TLCs allow manufacturers and regulators to quickly respond to food safety issues or contamination outbreaks. In such instances, time is critical.

Because TLCs remain unchanged until consumed or transformed, affected products can be rapidly traced back to their origin, bypassing the rest of the chain if needed. This targeted action mitigates risk, expedites investigations, reduces the time contaminated products remain on shelves, and limits the impact on public health and safety.

Enhanced traceability granularity leads to greater supply chain visibility and precise targeting for manufacturers and retailers during recall procedures, resulting in reduced waste and an improved recall cost profile.

In a nutshell, utilizing TLCs provides critical benefits, ensuring a safer and more efficient food supply chain.

To fully leverage TLCs, it's crucial to understand the role of transformations in the supply chain.



Understanding transformation

Transformation is defined as “an event in a food’s supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List.” – FDA, 2026

Whenever companies manufacture a new food product on this list, they must assign a new TLC to it, which always serves as a reference whenever the ingredient or food undergoes a transformation.

Repacking is always considered a transformation event. However, companies may not need to issue a new TLC if there has been no commingling of lots, and the repacking is done “like into like” (repacking the same product from one container into another without mixing different lots or when breaking down master cases from the same lot into smaller units).

There are six different TLCs for food supply chains:

- → New TLC for the food
- → Location description at point of transformation (the TLC source)
- → Date transformation was completed
- → Description of the food product
- → Quantity and unit of measurement of the food
- → Type and number of the reference document

When using foods from the FTL as ingredients in a transformation event, you must reference the ingredient’s TLC and specify the quantity and unit of measurement for each traceability lot used.



Leveraging traceability beyond compliance

The capacity to access comprehensive product data across the entire supply chain offers businesses plenty of positive externalities beyond compliance.

Traceable products mean securing food safety; executing targeted food recalls; rooting out counterfeit foods; gaining new insights into the food supply chain; ensuring product quality; facilitating consumer engagement opportunities; and introducing measurable sustainability efforts.

Compliance and the use of TLCs positively impacts relationships with consumers and other businesses in the supply chain by:

- → Demonstrating commitment to consumer safety, fostering trust and credibility with regulatory bodies, retailers, and consumers.
- → Improving integration of upstream and downstream suppliers, distributors, and retailers through seamless sharing of KDEs.

TLCs also serve as critical sources of data for informed decision-making, offering a holistic view of the supply chain. This meticulous traceability covers a product's lifecycle from origin to final destination, be it from farm to fork or grass to glass.

This level of detail and transparency empowers every stakeholder within the supply chain. It mitigates the risk of decisions based on insufficient or inaccurate information by providing precise, relevant data points tailored to each decision-maker's needs.

In the next section, we'll explore the cost versus benefit of implementing traceability systems.

Turning compliance into opportunity

The new age of traceability marks the evolution of the food supply chain industry.

For businesses involved, this means greater transparency, efficiency, accountability of operations, and better relationships with (up and downstream) suppliers, retailers, and consumers.

Additionally, the potential for more accurate, less wasteful recall processes lends itself well to sustainability and profitability.

At the end of every supply chain, there is better engagement and two-way communication between brands and consumers, where provenance, authenticity, ingredients, sustainability, recycling, and loyalty programs are all enhanced by traceability.

So, if the mindset collectively shifts from compliance to opportunity, we can unlock significant benefits across the entire supply chain, ensuring that your business is at the forefront of the next evolution in traceability.









How Kezzler solves FSMA 204

Kezzler's FSMA 204 solution

- → **Non-disruptive by design**
  Designed to integrate with, not replace, execution level and OT systems like ERP, WMS, MES, etc.
- → **Flexible data ingestion**
  API, ASN, EDI, EPCIS, file exchange, or manual entry. Every partner can contribute.
- → **Performance at scale**
  Billions of events. High-fidelity, low-latency retrieval when speed matters most.
- → **Extensible and flexible data schemas**
  Custom schemas beyond required KDEs so compliance data serves broader business needs.
- → **Retrieve, compile, organize, and provide by TLC**
  Exporting an electronic sortable spreadsheet in minutes — not hours.
- → **AI and future ready**
  MCP-ready architecture: compliance data becomes the foundation for AI insights.

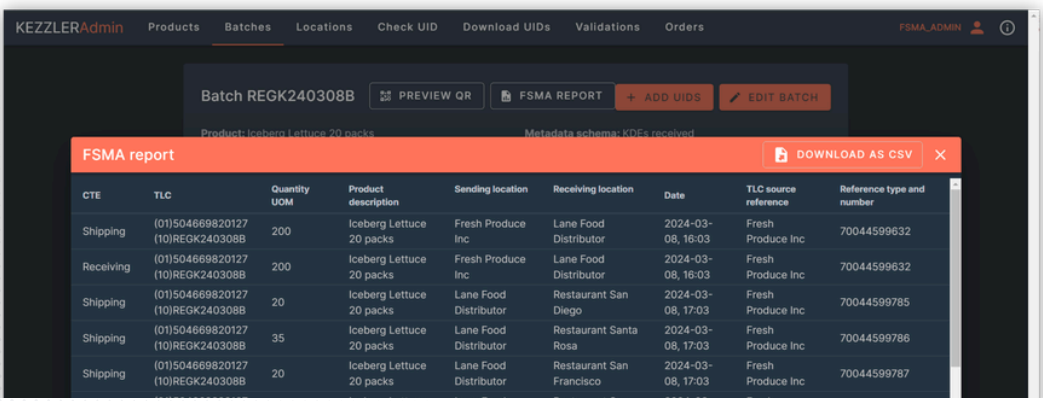
● About Kezzler

Founded in 2001, Kezzler is an established provider of product traceability, transparency, and consumer engagement solutions powered by connected product data. We help global brands achieve end-to-end value chain visibility, meet regulatory requirements, and deliver digital product experiences at scale.

Our scalable, standards-based platform allows brands to capture, connect, and share traceability data — without disrupting existing infrastructure.

FSMA 204 reports: every event, filterable and exportable

Filter by business step, batch, location or product. Search across billions of records and export what you need, when you need it.



CTE	TLC	Quantity UOM	Product description	Sending location	Receiving location	Date	TLC source reference	Reference type and number
Shipping	(01)504669820127 (10)REGK240308B	200	Iceberg Lettuce 20 packs	Fresh Produce Inc	Lane Food Distributor	2024-03-08, 16:03	Fresh Produce Inc	70044599632
Receiving	(01)504669820127 (10)REGK240308B	200	Iceberg Lettuce 20 packs	Fresh Produce Inc	Lane Food Distributor	2024-03-08, 16:03	Fresh Produce Inc	70044599632
Shipping	(01)504669820127 (10)REGK240308B	20	Iceberg Lettuce 20 packs	Lane Food Distributor	Restaurant San Diego	2024-03-08, 17:03	Fresh Produce Inc	70044599785
Shipping	(01)504669820127 (10)REGK240308B	35	Iceberg Lettuce 20 packs	Lane Food Distributor	Restaurant Santa Rosa	2024-03-08, 17:03	Fresh Produce Inc	70044599786
Shipping	(01)504669820127 (10)REGK240308B	20	Iceberg Lettuce 20 packs	Lane Food Distributor	Restaurant San Francisco	2024-03-08, 17:03	Fresh Produce Inc	70044599787

Trace every batch from raw material to retail shelf

See every ingredient and every location it shipped to. Backwards and forwards, in one view.



Contact us for a demo

A track record of successful implementation across verticals

Powered by 20+ years of global enterprise experience and backed by strong partners, Kezzler delivers high-volume traceability infrastructure tailored to complex, multi-system supply chains across verticals.

Retail

Kezzler gave a major grocery retailer near-real-time visibility across millions of daily transactions spanning produce, protein, dairy, and poultry, replacing data that had been fragmented across disconnected systems. That visibility now drives logistics optimization and waste reduction at scale.



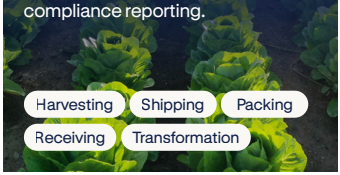
Dairy/CPG

Kezzler delivered farm-to-fork visibility across a 14-country dairy supply chain, connecting milking, production, packaging, quality, and logistics systems that had never spoken to each other into one cohesive digital thread.



Produce

Kezzler brought digital traceability within reach for small and medium-sized produce growers who lacked the technical infrastructure to support it, enabling shipping, receiving, and transformation data to be submitted through simple CSV uploads that Kezzler automatically validates, harmonizes, and prepares for compliance reporting.



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IDC Innovator 2024

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Have a look at our other resources

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Questions on FSMA 204 implementation and next steps?
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