

From Compliance to Opportunity: FSMA 204



What traceability means for your business.





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Achieve FSMA 204 compliance with advanced traceability

Imagine being a part of the next evolution of supply chains: compliant, transparent, and able to react to challenges with accuracy and efficiency, fostering higher trust and confidence with retailers, suppliers, and consumers alike.

That vision is already becoming a reality with our work alongside companies like yours.

But before we delve into how advanced traceability can ensure compliance with food safety standards and enhance operational efficiency, we'll explore what FSMA section 204 entails and its implications for your business and consumers.





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 Food Safety Modernization Act (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 traceability. 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.





Why traceability matters

To truly understand the impact of the FSMA 204 rule, it's important to grasp why traceability matters. If you're making operational decisions, you need information on things like batch numbers, time picked or packed, and stock levels—this is where Key Data Elements (KDEs) come in. KDEs are critical pieces of information attached to products, helping us 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. They can record what happened and when, from harvesting or production through processing, distribution, and receipt.

KDEs and CTEs must be added 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:

1. Harvesting
2. Cooling before initial packing
3. Initial packing of produce or aquaculture food
4. First land-based receiver for food obtained from a fishing vessel
5. Shipping
6. Receiving
7. Transformation

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





Shipping & 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
- Location description of the immediate previous source (other than a transporter)
- Location description of where the food was received
- Description of the food product
- 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 Food Traceability List (FTL) designates the initial foods subject to enforcement. The extensive list can be found on the FDA's website² and will evolve over time.



Cheeses



Shell eggs



Nut butters



Leafy greens



Tomatoes



Tropical fruits



Finfish



Crustaceans



Mollusks



and more...





FSMA 204 Traceability Challenges



Variety of product data across SKUs

Managing different Key Date Element (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, necessitating robust systems to manage and link these points for accurate traceability.



24-hour data collation deadline

Information must be ready to be collated and presented 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.

A man with a beard, wearing a checkered shirt and jeans, is standing in a field of green plants. He is looking down at a smartphone in his hands. The background is a bright, hazy sky.

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 (e.g., Shipping, Receiving, and Transformation KDEs are likely stored across a wide assortment of 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.

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 Traceability Lot Codes (TLCs), which we'll dive into next.



What are TLCs, and are they crucial?

Traceability Lot Codes (TLCs) are essential for FSMA 204 compliance and ensuring the integrity of the entire supply chain.

Each TLC is the anchoring element of a digital thread that details a product's journey from production to distribution and sale.

These unique identifiers 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.
- **Key Data Elements (KDEs) attached to the product**
specified within FSMA 204 for a particular Critical Tracking Event (CTE)



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:

- A randomized alphanumeric string.
- A GTIN combined with other relevant Application Identifiers (AIs). For example, a batch ID (forming an LGTIN) or a GTIN in combination with the product's expiration date.
- 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.

We recommend considering TLCs that align as closely as possible with GS1 standards and leverage their nomenclature.



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.
- 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.

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

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.



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 accountability 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.” – FSMA 204

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).

Transformation related to the production of new food products requires the collection of the following KDEs:

- **New TLC** for the food
- **Location** description at point of transformation (the traceability lot code source)
- **Date** transformation was completed
- **Product description** for the food
- **Quantity** and **unit** of measurement of the food
- **Type and number** of the reference document



When using foods from the Food Traceability List 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 Key Data Elements.

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.





Cost vs. benefit

While traceability offers significant benefits, there is a trade-off with item-level identifiers: they are more expensive to implement but allow precise targeting of affected products and locations, enabling highly targeted recalls.

This level of granularity may not be possible for operators using legacy standards like EDI 856 to share supply-chain information due to the inherent nature in which that ASN is constructed.

However, where feasible, granularity makes sense. More targeted recalls result in less waste, saving time, money, and preserving brand perception.

Think of the granularity of your Traceability and Transparency (TLC) system like the pixelation of an image: finer granularity provides higher resolution, while grouping more items under the same TLC increases pixelation. Higher resolution enhances clarity regarding your supply chain, improving forecasting, optimization, and the development of precise supply chain digital twins, turning compliance costs into a value-generating opportunity.

Now, let's explore how shifting your perspective from compliance to opportunity can unlock even greater benefits.



Turning compliance into opportunity

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

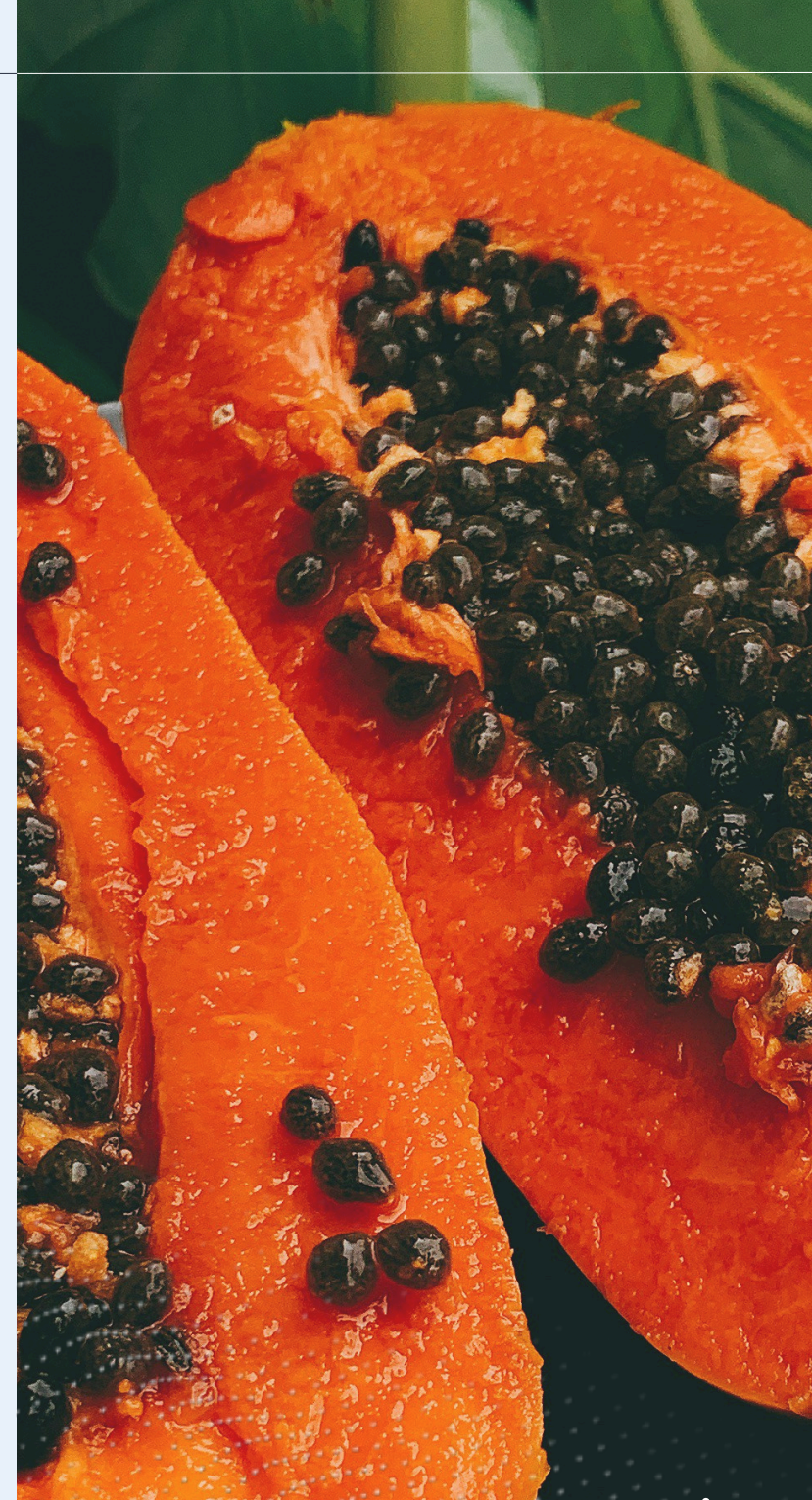
For businesses involved, this means greater transparency, efficiency, accountability of operations, and better relationships with (up and downstream) suppliers and retailers.

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.

We achieve this by forging strategic collaborations with industry leaders, enabling us to integrate cutting-edge solutions and drive innovation in traceability.





Strategic Collaboration

It's uncommon for a single company to excel at intuitive mobile data capture, scalable data integrations, and international support services.

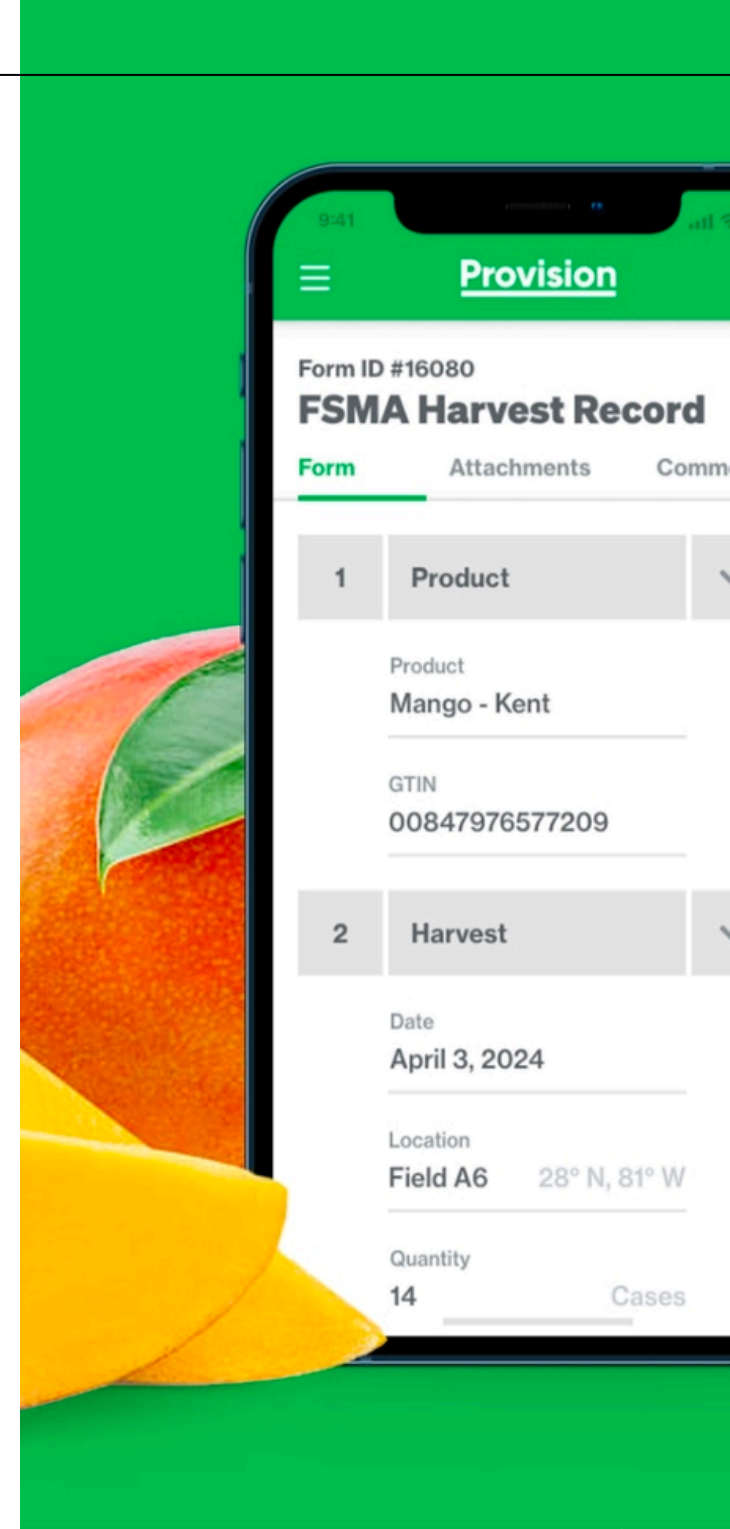
Food distributors should consider adopting a best-in-breed strategy, selecting top solutions for each of these three areas. To achieve this, Kezzler (a winner of the FDA Traceability Challenge) has partnered with Provision and DNV¹. This collaboration enables distributors to organize and consolidate varied data from a network of small suppliers, seamlessly integrating it into multiple Provision accounts.

Provision

Provision offers an intuitive, mobile-first platform for compliance documentation, helping small suppliers become audit-ready 54% faster than before. Its cloud software simplifies food safety and quality assurance across the produce industry by replacing paper records with smart tools, reducing stress, and streamlining audit preparation. Automatic reminders, notifications, and tailored smart rules empower growers, packers, and distributors with agile, efficient solutions.



DNV, operating in over 100 countries, provides independent assurance and risk management services. Specializing in product certification, claim verification, and supply chain optimization, DNV enhances trust and transparency across products, assets, and ecosystems. Combining sustainability with digital insights, the company develops new assurance models, promoting clear interactions within value chains. Committed to safeguarding life, property, and the environment, DNV addresses global challenges and fosters trust globally.





Strategic Collaboration



We are proud to partner with Rockwell Automation, a global leader in industrial automation and digital transformation, to extend the FSMA 204 traceability umbrella in the food processing and manufacturing space. We are revolutionizing traceability by combining Kezzler's expertise in supply chain data management solutions with Rockwell Automation's cutting-edge smart manufacturing solutions (such as Plex and FactoryTalk).

The seamless integration between our solutions enables producers and manufacturers to consolidate processing and factory data across the supply chain. Together, Kezzler and Rockwell are taking traceability beyond the traditional one-up/one-down framework.





Kezzler

Kezzler is a software company and technology leader specializing in providing Digital ID solutions for connected products. Since 2001, Kezzler has powered product digitization and helped build sustainable value chains for global businesses across industries as varied as food and beverage, fashion and apparel, industrial goods, OTC pharmaceuticals, and consumer packaged goods.

Kezzler is headquartered in Oslo, Norway with a global footprint, serving customers in Europe, North America, and Asia. Learn more at www.kezzler.com.

Connected Products Platform

Kezzler's Connected Products Platform (CPP) is a managed SaaS solution that enables businesses to manage, control, and add value to their products throughout their entire journeys. By assigning unique Digital IDs to individual items, the platform provides real-time visibility, authentication, and connected experiences. With its agnostic approach to systems and platforms, Kezzler's platform seamlessly integrates with existing IT infrastructure, offering a scalable and flexible solution configurable to their needs.

Get in touch with Kezzler to learn more about the Connected Products Platform and how we can help you digitize your food and beverage products.



Massively Scalable

46bn

USD value of goods digitized last 12 months

Flexible & Fast

5m

daily platform interactions on one single client's software

Integration Friendly

30bn

connected products as of 2023

Purpose Built

>35

countries with activated products in the market

HQ | Norway

Schweigaards gate 15b 0191
Oslo

The Netherlands

Gamerschestraat 47 5301
AR Zaltbommel

India

Level 4 MBC Infotech Park
Maharashtra

Singapore

11 North Buona Vista Drive,
Metropolis, #08-09, 138589

China

Room 805,7/F No.1 Building
Chaoyang District, Beijing

USA

One Marina Park Drive Suite
1410, 02210 Boston



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