



***FORWARD
IN FOCUS***

Practical Steps for Complying with FDA's FSMA 204 Food Safety Traceability Rule

September 15, 2026

Jared Keefer (Shamrock Foods), Charles Leftwich (Sysco Corp.),
Ceret Leyva (Ben E. Keith Co.)

Sponsored by:





FSMA 204 Traceability Rule Overview

Food Traceability List





FSMA 204 CRITICAL TRACKING EVENTS for a Food Distribution Company



Food Traceability Rule – Key Data Elements (KDEs) required for foods
on the Food Traceability List (FTL)



RECEIVING CTE

Incoming product from supplier



Incoming shipment
from supplier



Inspection and
verification



Temperature-
controlled receiving

REQUIRED RECORDS (linked to Traceability Lot Code)

- TLC
- Product description
- Quantity & unit of measure
- Date received
- Location description of receiving facility
- Location description of TLC source
- Reference document type & number



Accurate records at receiving ensure
full traceability from source to facility.



TRANSFORMATION CTE (if applicable)



Only if distributor commingles, repacks,
or relabels creating a new FTL lot.



New TLC assigned



Link incoming TLC(s) to new outgoing TLC



SHIPPING CTE

Product leaving for customer / next recipient



Outbound shipment
to customer /
next recipient



Temperature-
controlled
shipping



Proper loading
and documentation

REQUIRED RECORDS (maintain AND provide to immediate subsequent recipient)

- TLC
- Product description
- Quantity & unit of measure
- Date shipped
- Location description of shipping facility
- Location description of immediate
subsequent recipient



Accurate records at shipping ensure
traceability continues through
the supply chain.



Traceability Lot Code (TLC) must link all events.



Records must be sortable/electronic and
provided to FDA within 24 hours of request.



Source: FDA Food Traceability Rule, 21 CFR Part 1 Subpart S.

FSMA 204 Key Data Elements (KDEs)

Food Traceability Rule — Records that must be linked to the **Traceability Lot Code (TLC)** for foods on the Food Traceability List (FTL)



RECEIVING KDEs

Traceability lot code (TLC)

- Product description
- Quantity and unit of measure
- Date food is received
- Location description of the receiving facility
- Location description of the immediate previous source (other than transporter)
- Location description for the TLC source (or TLC source reference)
- Reference document type and number



TRANSFORMATION KDEs (if you create a new lot)

New TLC assigned to the output food

- Product description of output
- Quantity and unit of measure of output
- Date transformation completed
- Location description where transformation occurred
- Input TLC(s) and product descriptions of FTL foods used
- Reference document type and number



SHIPPING KDEs

Maintain AND provide to immediate subsequent recipient

- Traceability lot code (TLC)
- Product description
- Quantity and unit of measure
- Date food is shipped
- Location description of the shipping facility
- Location description of the immediate subsequent recipient (other than transporter)
- Location description for the TLC source (or TLC source reference)
- Reference document type and number (maintain)



UPSTREAM / ORIGIN KDEs

(usually provided by farms, packers, first land-based receivers)



Harvest / Cooling / Initial Packing extras include:
commodity & variety, farm and field/growing area location,
harvest date, cooler location and date cooled, harvester
name & phone, fishing vessel / landing info for seafood.



All KDEs must be linked to the TLC.



Records kept 2 years, sortable/electronic,
available to FDA within 24 hours.

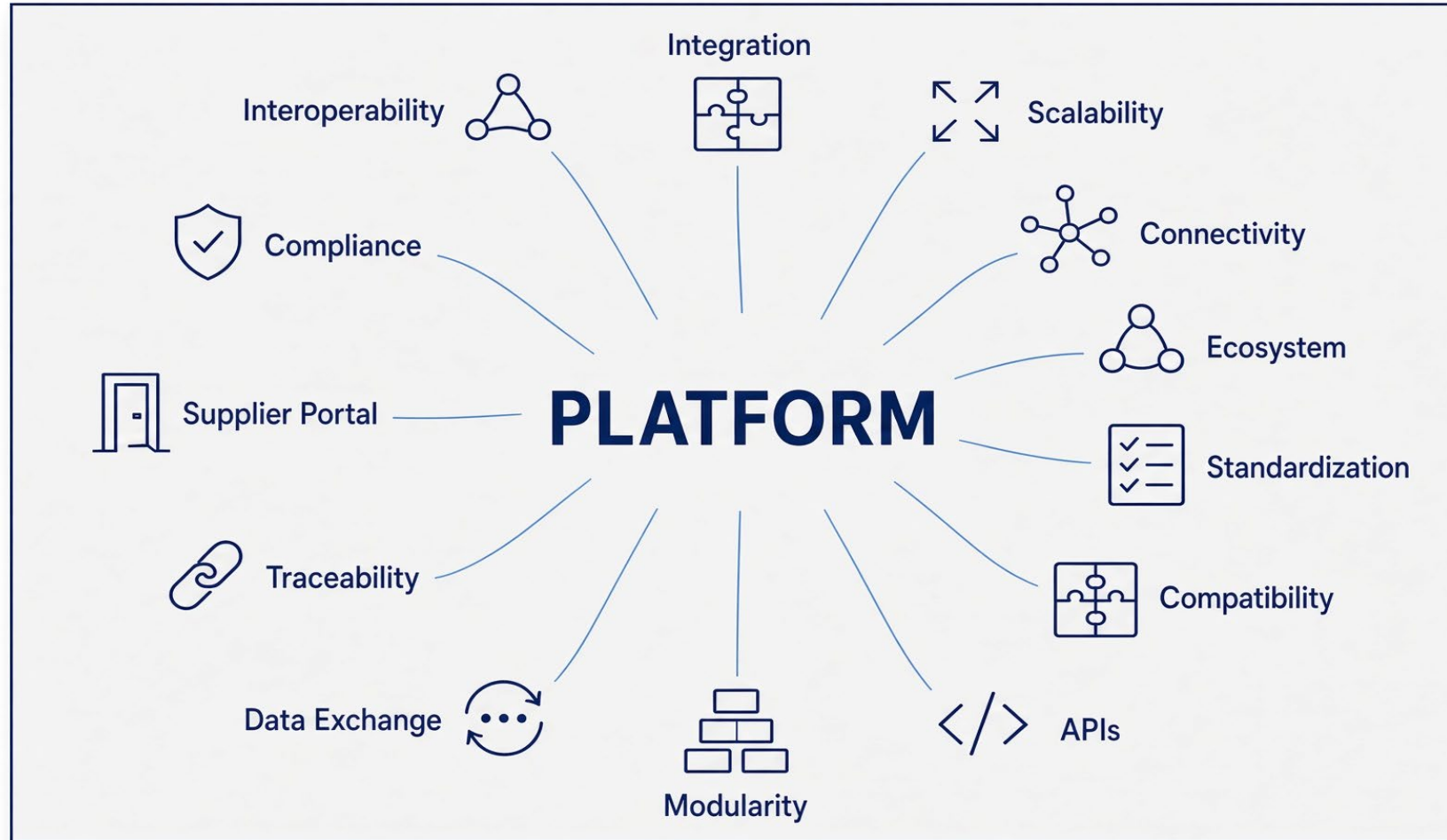


Source: FDA Food Traceability Rule, 21 CFR
Part 1 Subpart S (§§ 1.1325–1.1350).



Platforms/Software

Platforms/Software



Data



Scanning	EDI	Tabular
GS1-128	ANSI	XML
SSCC	ASN	CSV

Data Elements per Traceability Lot Code – Collected – Stored
Events: Receiving, Transformation (if any), & Shipping



GS1 – FSMA 204 Rule Distributor Pilot

Overview

The GS1 US Food Safety Modernization Act Rule 204 (FSMA Rule 204) Distributor Pilot provides a data-driven baseline of how traceability data is currently received and stored across food distributors. By analyzing approximately 880,000 data records from real distributor-supplier transactions, this study offers a clear view of industry readiness for FSMA Rule 204 requirements.

Participating distributors included:

- Dot Foods
- Gordon Food Service
- Performance Food Group
- Sysco
- Texas-based Food Product & Alcoholic Beverage Distributor

The pilot evaluated both the presence of data and completeness of the data. Data completeness focused on whether it was usable, correctly formatted, and aligned to FDA requirements across all KDE categories.

The findings show that while core transactional data is consistently strong, critical gaps remain in traceability-specific data, particularly in Traceability Lot Code (TLC) capture, product description completeness, and the use of standardized identifiers¹.

This report establishes a shared starting point for the industry to align, standardize, and strengthen traceability practices ahead of FSMA Rule 204 deadlines.

Methodology

GS1 US analyzed inbound supplier data provided by multiple food distributors, reflecting how data is received, stored, and shared within existing systems. The study analyzed data as received from distributors and did not independently verify it against suppliers or trading partners.

The analysis included:

- Data from multiple distributors and approximately 600 suppliers.
- Over 880,000 data records sourced primarily from transactional records.
- Mapping of data fields to FSMA Rule 204 Key Data Elements (KDEs).

Each data element was evaluated across three dimensions:

- Presence: Whether the data exists.
- Completeness: Whether the data meets required structure and format.
- Accuracy: Whether identifiers are valid.

This approach allowed GS1 US to go beyond surface-level analysis and identify where data may exist but still fall short of traceability requirements.

Findings

The FSMA Distributor Pilot revealed a set of consistent, data-driven patterns across participating organizations. These findings highlight both areas of strength and concentrated gaps that directly impact traceability readiness.

Image 1 - Aggregated Results of Populated Fields KDE Presence & Completeness (Normalized)

KDE Presence (Normalized)												
Supplier	GTIN	TLC	Qty	Unit of Measure	Product Desc	Prev Loc. Desc.	Recv Loc. Desc.	Date Received	TLC Src	TLC Src Ref	Ref Doc Type	Ref Doc #
#1	80	40	100	100	80	74	94	94	20	20	100	100
#2	75	50	100	100	75	100	96	100	25	25	100	100
#3	67	67	100	100	87	100	83	83	49	66	100	100
#4	39	33	99	100	100	67	100	100	0	0	100	100
#5	50	50	100	100	100	100	100	100	50	50	100	100
#6	0	0	100	100	100	100	90	100	0	0	100	100
All	71	50	100	100	86	80	98	99	16	17	100	100
KDE Completeness (Normalized)												
Supplier	GTIN	TLC	Qty	Unit of Measure	Product Desc	Prev Loc. Desc.	Recv Loc. Desc.	Date Received	TLC Src	TLC Src Ref	Ref Doc Type	Ref Doc #
#1	68	40	100	100	0	72	34	94	0	20	100	100
#2	66	50	100	100	0	65	50	100	0	25	100	100
#3	67	67	100	100	0	80	50	83	16	58	100	100
#4	27	33	99	100	0	61	0	100	0	0	100	100
#5	50	50	100	100	0	96	50	100	50	50	100	100
#6	0	0	100	100	0	82	0	100	0	0	100	100
All	57	50	100	100	0	70	38	99	2	9	100	100

Takeaways

For organizations preparing for FSMA Rule 204, the implications are clear:

You are not starting from scratch

Much of the required data already exists in current systems. The opportunity lies in improving quality, consistency, and alignment.

Data usability is a key challenge

Incomplete or inconsistent data carries the same risk as missing data. Prioritizing data quality is essential.

Supplier alignment is critical

Variability in upstream data highlights the need for stronger agreements and shared expectations between trading partners.

Standardization unlocks scale

Using global identifiers (e.g., GTINs, GLNs) reduces manual effort and enables reliable data exchange across systems.

Targeted improvements deliver impact

Because gaps are concentrated, focusing on a few key areas can significantly improve overall traceability readiness.

Reference: GS1 US FSMA Rule 204 Distributor Pilot Findings and Takeaways

Q&A