



From KDEs to CTEs and Beyond: Ensuring FSMA 204 Compliance

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Provision Analytics & GS1 US

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Retail Grocery & Foodservice

Using GS1 Standards for FSMA 204

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IDDBA
April 8, 2025





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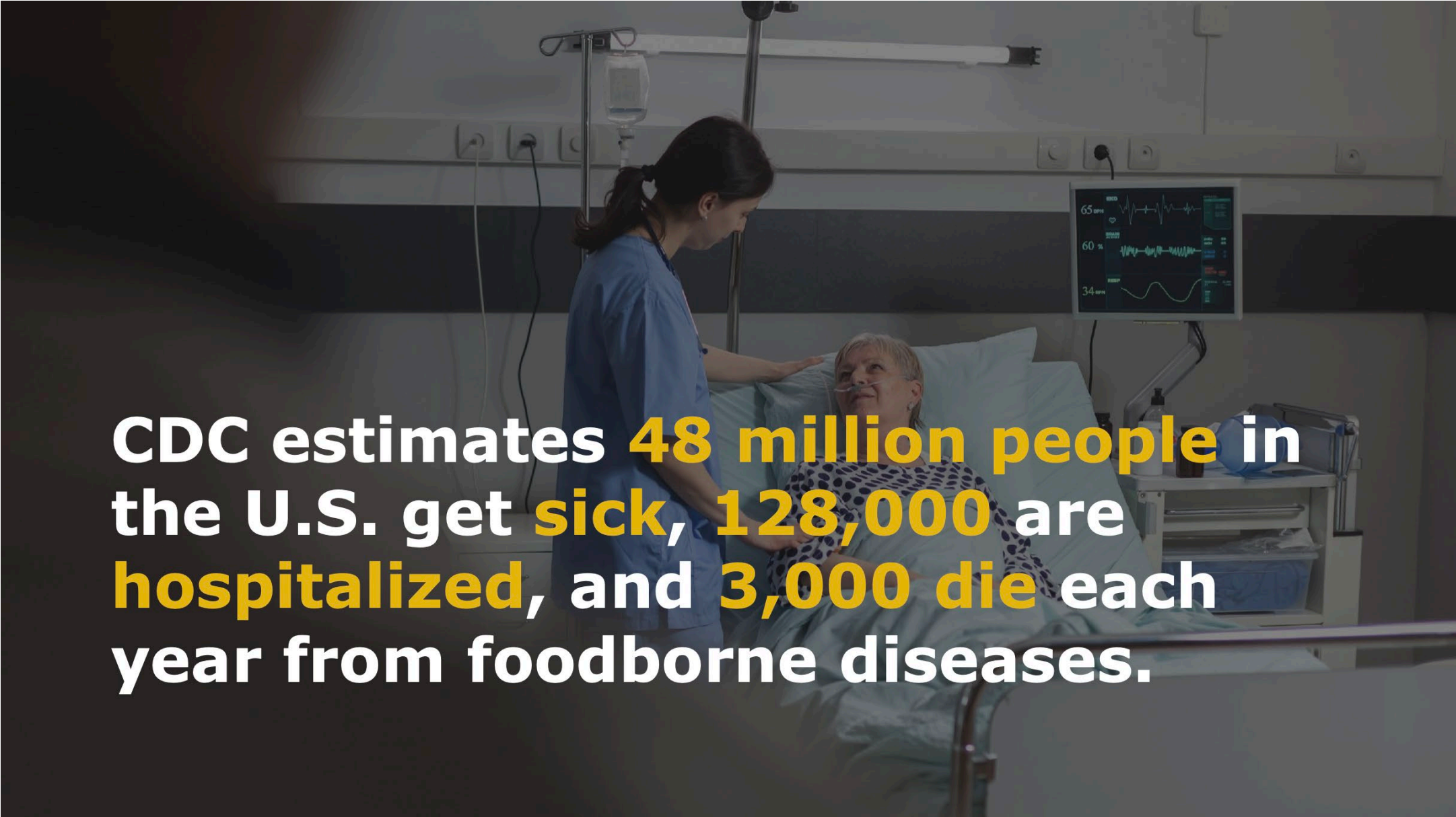
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CDC estimates **48 million people** in the U.S. get **sick**, **128,000** are **hospitalized**, and **3,000 die** each year from foodborne diseases.

Food Safety Modernization Act Rule 204 Basics

What is it and who is impacted?

- Establishes Requirements for Additional Traceability Records for high-risk products outlined in the **Food Traceability List (FTL)**
- Anyone who manufactures, processes, packs, or holds foods
- Full and partial **exemptions may apply**

What is required?

- Must keep records on foods from Farm to Store/Restaurant by **production LOT**; supply chain partners need to share records
- Provide **Critical Tracking Events (CTEs) and Key Data Elements (KDEs) to U.S. Food and Drug Administration (FDA) within 24 hours** in a sortable spreadsheet
- Must keep a documented **Traceability Plan**

When?

- Final Rule Effective: January 2023
- Compliance Date: June 2028
- Records should be maintained for 2 years

Food Traceability List



Cheese
(other than hard
cheeses)



Crustaceans
(fresh and frozen)



Cucumbers
(fresh)



Finfish
(fresh and frozen)



Fruit
(fresh cut)



Herbs
(fresh)



Leafy Greens
(fresh)



Leafy Greens
(fresh cut)



Melons
(fresh)



**Molluscan
Shellfish Bivalves**
(fresh and frozen)



Nut Butters



Peppers
(fresh)



**Ready-to-Eat
Deli Salads**
(refrigerated)



Sprouts
(fresh cut)



Shell Eggs
(fresh)



**Smoked
Finfish**
(refrigerated
and frozen)



Tomatoes
(fresh)

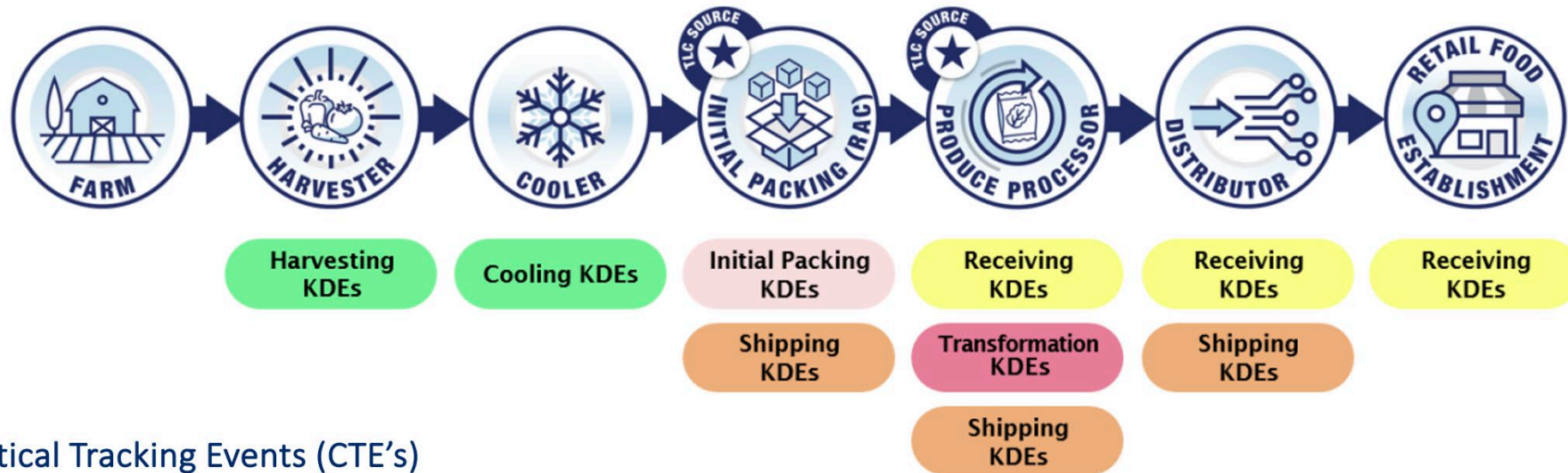


**Tropical
Tree Fruit**
(fresh)



**Vegetables
Other Than
Leafy Greens**
(fresh cut)

FDA Supply Chain Example: Produce



Critical Tracking Events (CTE's)

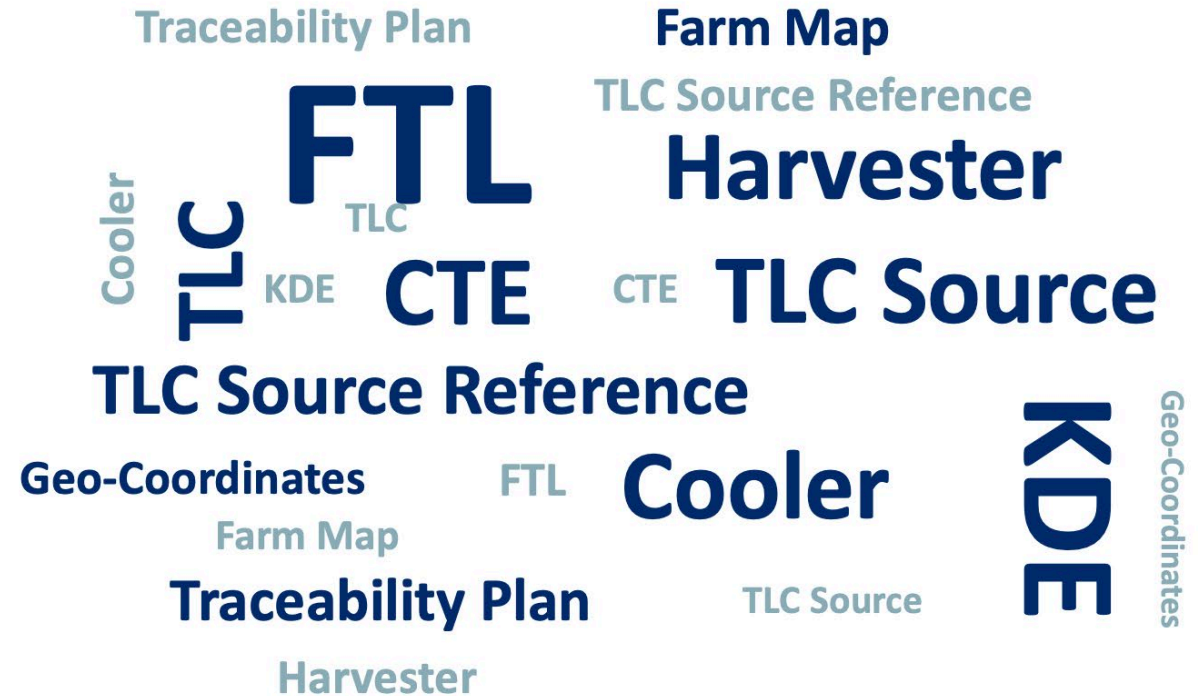
Activities or actions that occur in a food supply chain

Key Data Elements (KDE's)

Data attributes that describe the CTE: What, Where, When, Who, Why

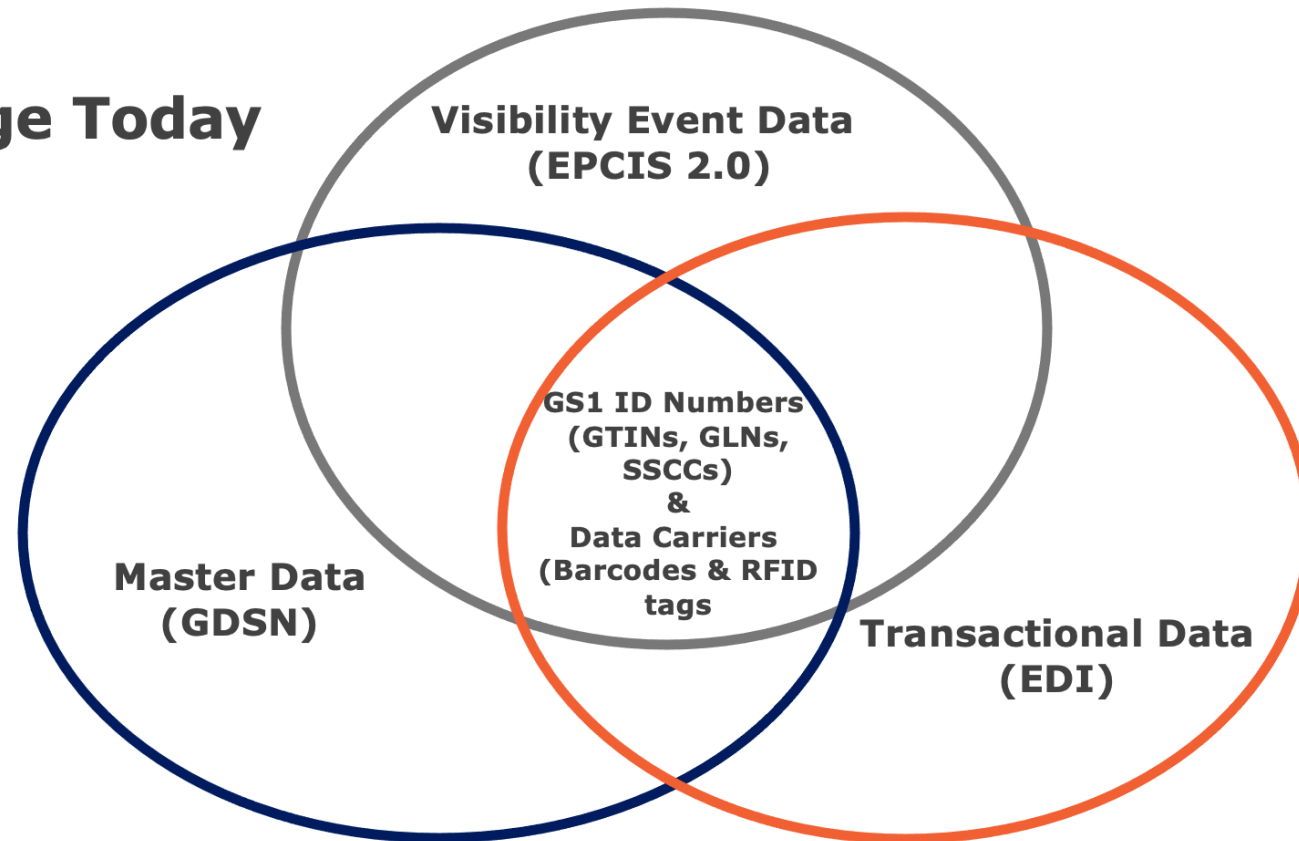
Leveraging GS1 Standards for FSMA 204

GS1 US Supporting the Food Industry



GS1 US Supporting the Food Industry

Data Exchange Today



* Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards.
For more information refer to x12.org/products/transaction-sets

FSMA 204 Detailed CTEs-KDEs

1. Harvesting
2. Cooling
3. Initial Packing
4. First Land-Based Receiver (*Seafood*)
5. Shipping
6. Receiving
7. Transformation

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

Harvesting

Cooling
(before Initial Packing)

Initial Packing
(RAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

Receiving KDEs
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

Receiving KDEs
For food you receive from a person who is exempt from the rule
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e, traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

Source: [FDA.gov](https://www.fda.gov)

Master Data & Event Data

Master Data

Additional Identifier: GTIN®*

- Product Name
- Brand Name
- Commodity
- Variety
- Packaging Size
- Packaging Style
- Species (seafood)
- Market Name (seafood)

GDSN®

Additional Identifier: GLN*

- Business Name
- Primary Phone Number
- Physical Location Name
- Physical Location Address
- Growing-Area Coordinates (farm)
- Company Contact
- Phone
- City
- State
- Postal Code

GS1 US Data Hub | Location*

Transactional/Event Data

Additional Identifier: GTIN, GLN, SSCC*

- Event Date
- Quantity & Unit of Measure
- Reference Records
- Product & Location Descriptions
- Traceability Lot Codes
- Assignment Method
- Point of Contact
- Reference Record Type & Identifier

EPCIS/EDI*

* Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards.
For more information refer to x12.org/products/transaction-sets

How GS1 Standards Work for FSMA 204



Identify

- **Product**
Global Trade Item Number® (GTIN®)
- **Pallet**
Serial Shipping Container Code (SSCC)
- **Location/Party**
Global Location Number (GLN)



Capture

Data carriers that allow for the addition of lot codes:

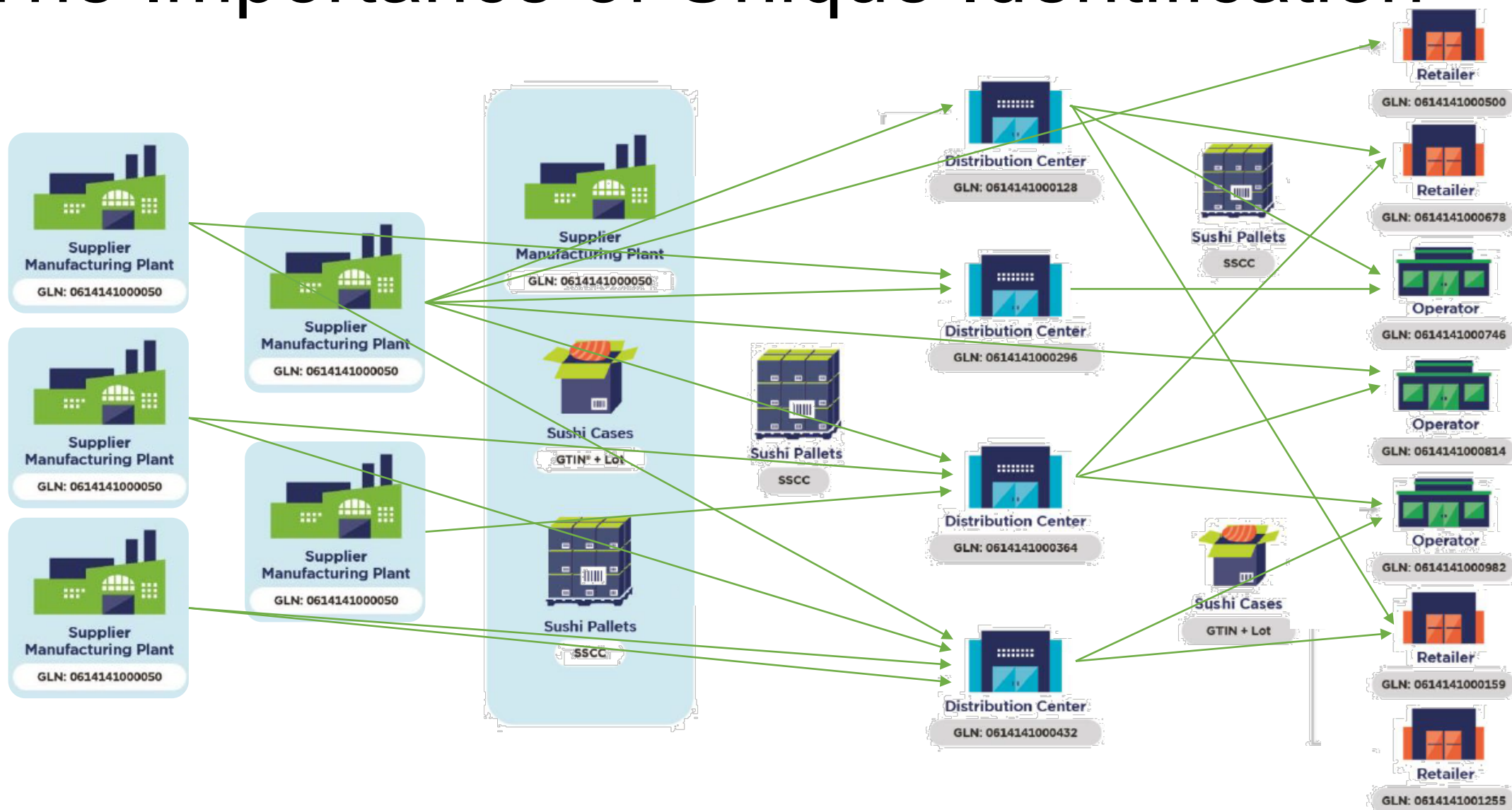
- **Barcodes**
 - GS1-128 , 
 - GS1 Data Matrix
- **RFID Tags**
 - RAIN radio frequency identification (RAIN RFID) 



Share

- **Product Data Exchange**
GDSN
- **Location Data Exchange**
GS1 US Data Hub | Location - View/Use
- **Event Data Exchange**
Electronic data interchange (EDI), Electronic Product Code Information Services (EPCIS)

The Importance of Unique Identification





FSMA Rule 204 and Applicable Standards

REQUIREMENTS

SOLUTIONS

Identify FTL Items & Product Description KDEs	GTIN and GDSN▶
Parties & Locations Description KDEs	GLN and GS1 US Data Hub▶
Shipping KDEs	ASN (EDI 856)*▶
All Other CTEs/KDEs	EPCIS▶
Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain	Data Carriers, ASNs, EPCIS▶
Connecting Master Data to Transactional and Event Data ▶	

*Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets

FSMA Rule 204 and Applicable Standards

REQUIREMENTS

Identify FTL Items & Product Description KDEs

Parties & Locations Description KDEs

SOLUTIONS

GTIN and GDSN▶

GLN and GS1 US Data Hub▶

Shipping KDEs

ASN (EDI 856)*▶

All Other CTEs/KDEs

EPCIS▶

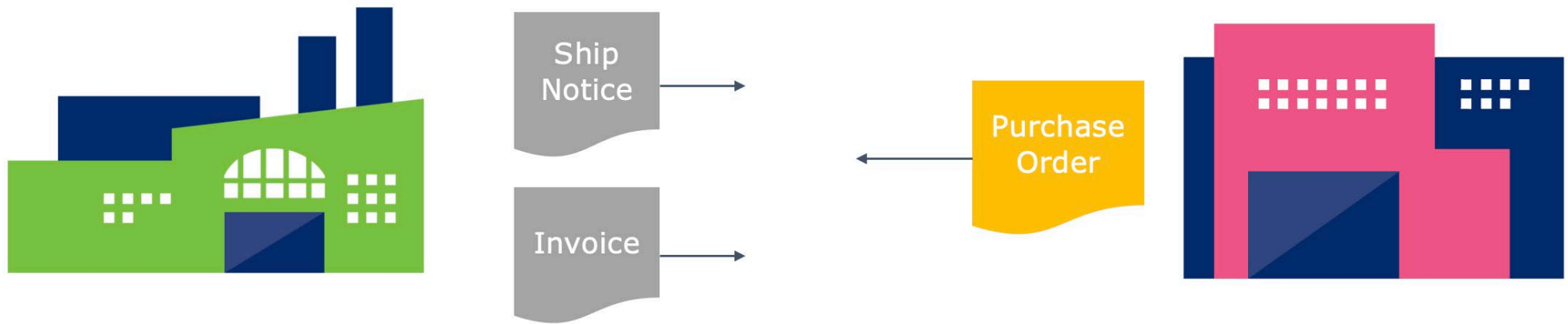
Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain

Data Carriers, ASNs, EPCIS▶

Connecting Master Data to Transactional and Event Data ▶

*Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets

Transaction Data

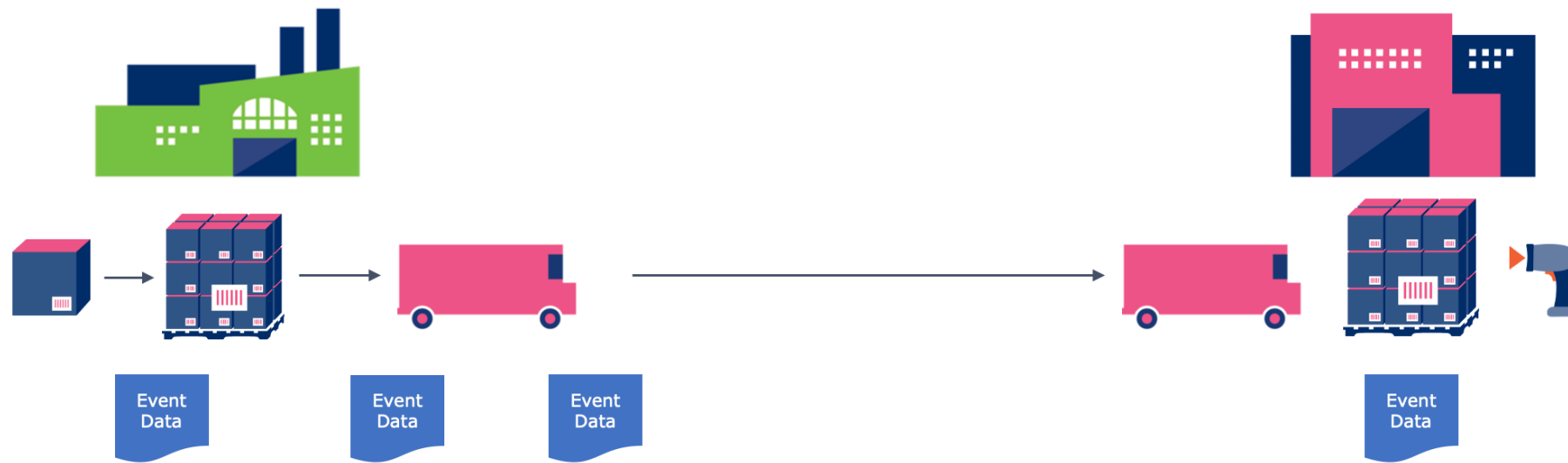


Business information required to support a collaborative business process shared bilaterally between organizations

Confirm legal or financial interactions between trading partners

Each document confirms the commitment to execute the agreement

Visibility Event Data



Records of the completion of business process steps in which physical or digital entities are handled

Confirm the carrying out of a physical process or a comparable digital process

Provides a current or historic snapshot of the location or condition of an object(s)

What is EPCIS?

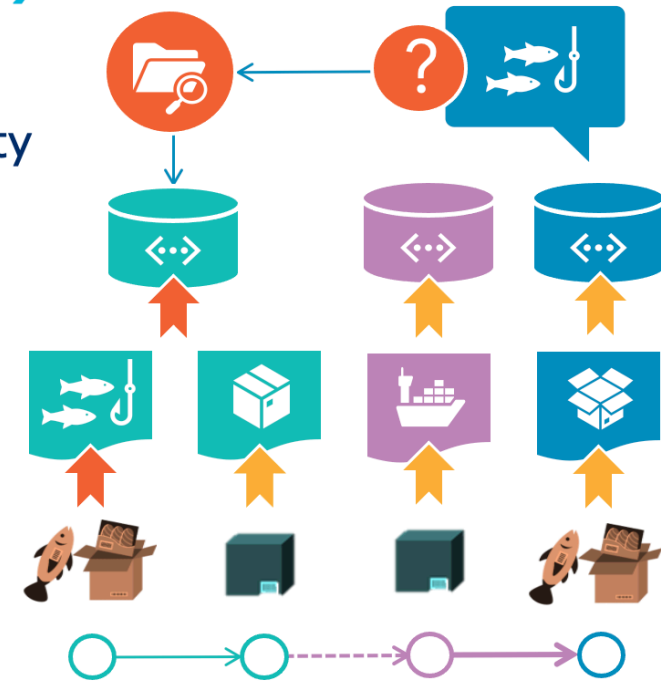
Electronic Product Code Information Services (EPCIS)

A **GS1 standard** that defines;

- A common language and framework for building visibility event data and visibility systems
- Interfaces for capturing, querying, sending data

The **Goal** of EPCIS is to;

- Enable disparate applications to create and share visibility event data
- Both, within and across enterprises.

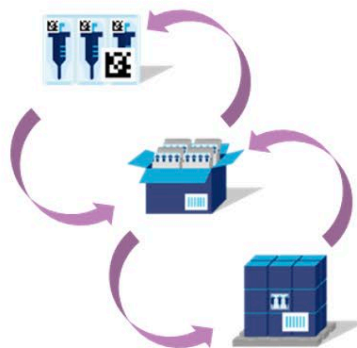


EPCIS Event Types

Object



Aggregation



Transformation



Transformation CTE & EPCIS



EPCIS Event Dimensions



Scan barcode or read RFID tag to capture the event

FSMA Rule 204 and Applicable Standards

REQUIREMENTS

Identify FTL Items & Product Description KDEs

Parties & Product Description KDEs

REQUIREMENT

SOLUTIONS

GTIN and GDSN>

GLN and GS1 US Data File>

SOLUTION

Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain

Data Carriers, ASNs, EPCIS>

All Other CTEs/KDEs

EPCIS>

Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain

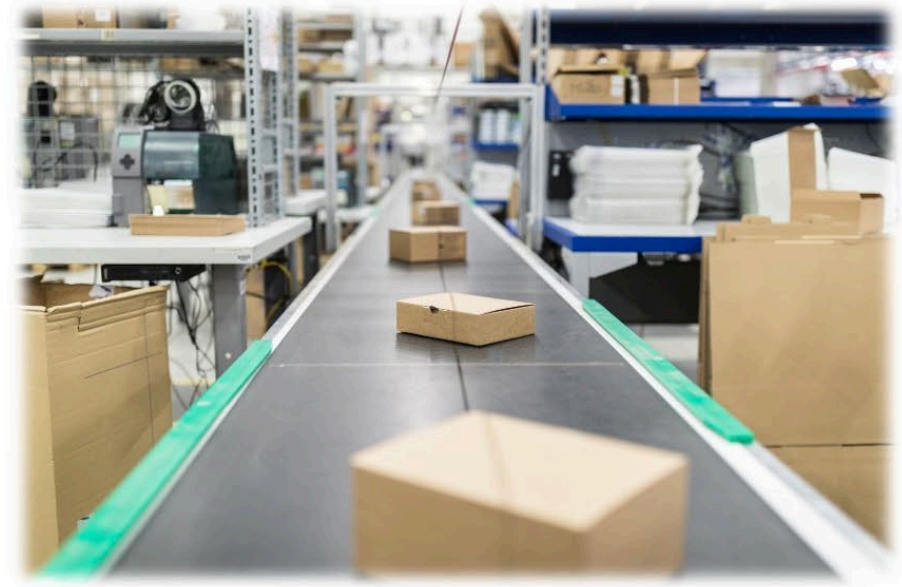
Data Carriers, ASNs, EPCIS>

Connecting Master Data to Transactional and Event Data >

*Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets

TLC Source & TLC Source Reference Definitions

- **Traceability Lot Code (TLC)**
 - batch/lot, typically alphanumeric
- **TLC Source**
 - The location where a food was assigned the TLC
 - KDEs: **TLC Source Location Description**
- **TLC Source Reference**
 - Method for giving FDA access to the TLC Source Location Description information
 - FDA Examples: “FDA Facility Registration Number, GLN, web address in a QR Code, GS1 Digital Link”

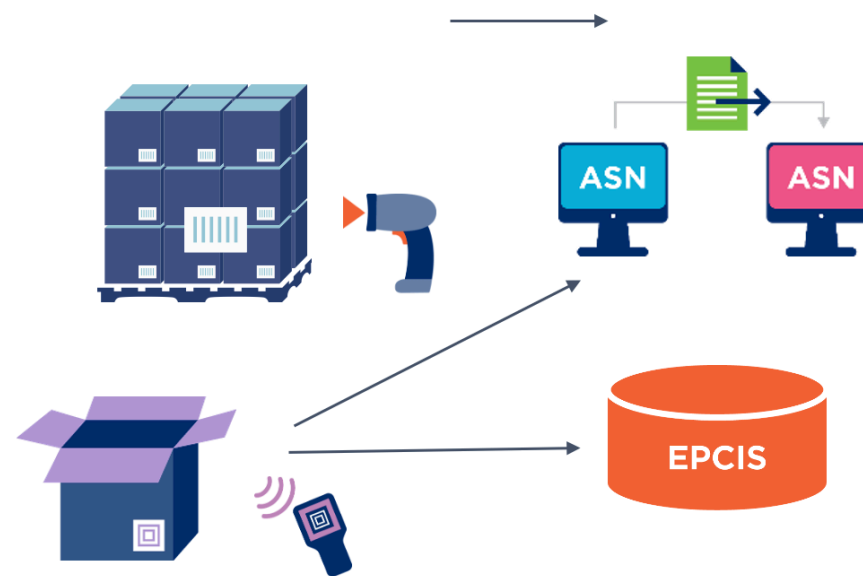


Source: [federalregister.gov](https://www.federalregister.gov)

Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain

Best Practice:

- **TLC = GTIN: AI(01) + Lot: AI(10)**
- A **GLN** can be used to determine the **Traceability Lot Code (TLC) Source Reference**.



Can be captured/shared in the data carriers, ASN, and EPCIS events

GS1-128 Barcode



=010085000600000517151
231320200522510987654

Flags:

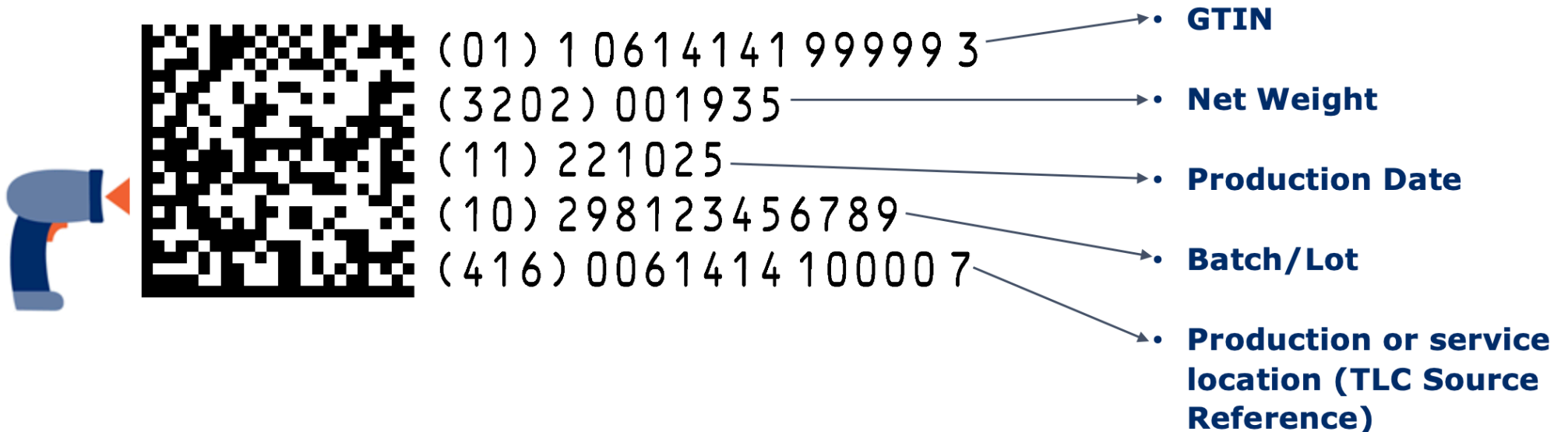
- Identify the type of data
- Defines the format/length
- Assists in the routing of data



GTIN	Expiration Date	Net Weight	Batch/Lot Number
00850006000005	December 31, 2015	52.25	987654

GS1 Data Matrix

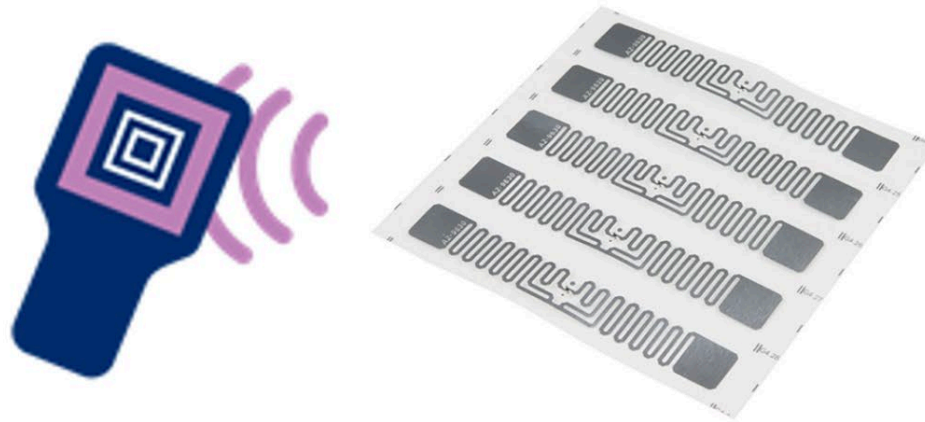
GTIN + Additional Attributes, with a 2,335-character limit, uses same data syntax as GS1-128



RFID

Include GTIN + Date + batch/Lot for food traceability

High-speed inventory visibility without line-of-sight scanning.

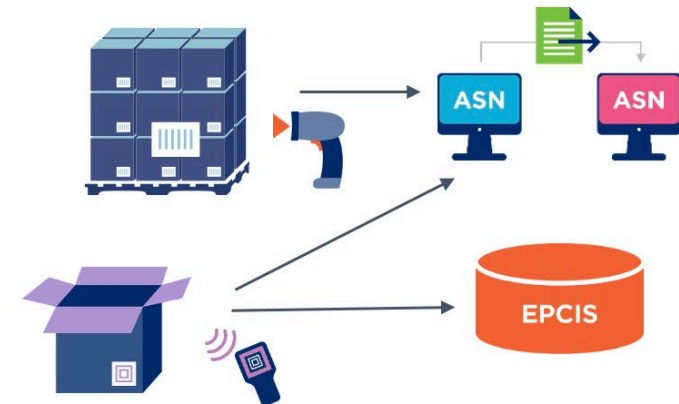


Capture TLC & TLC Source Reference Throughout Supply Chain

Reference Guidelines

Sections 2.2-2.3 of the GS1 FSMA Rule 204 Guideline explain best practice to capture TLC and TLC source throughout the supply chain.

Section 3.2.2 of the GS1 FSMA Rule 204 Guideline explains the different data carriers that could be used, such as GS1-128 barcodes, 2D barcodes, and RFID tags.



[View sections 2.2-2.3 and 3.2.2 of the GS1 US FSMA Rule 204 Guideline >](#)

[View NA Case Labeling Guideline for GS1-128 information >](#)

[View 2D Barcode Overview in General Distribution >](#)

[View RFID Foodservice Implementation Guideline >](#)

ROI

Information

- Accurate information drives sales
- Clean data saves time, money, and resources

Product

- Less product waste
- Ability to better identify affected lots for recall
- Better freshness management

Process

- Greater efficiency/transparency via automation
- Enhanced consumer safety

Consumer Engagement

- Brand loyalty
- Additional safety



More Than Meeting Regulation...



64,794 restaurants
were contacted
during **11** quality
incidents

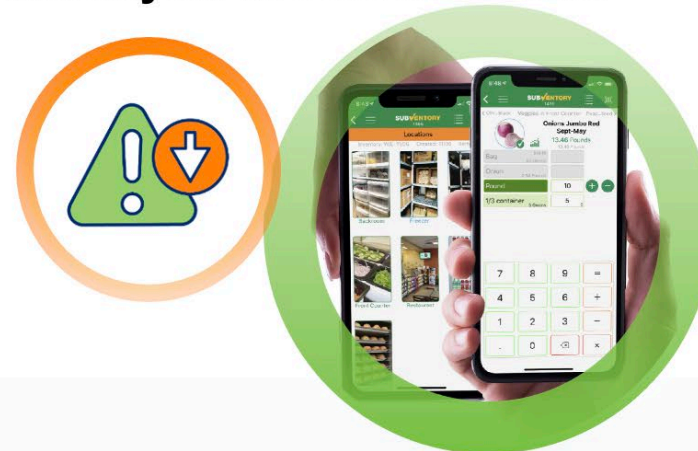
Traceability enables annual potential savings



9,259 hours
of labor | more than
\$110K

**\$1.3 Million in annual cost avoidance
from Master Data cleanup with GDSN**

**Eliminating pain for more than 24,000
restaurants using GS1 Standards
\$72 million/year in cost avoidance**



[GS1 US Case Study: IPC/Subway Delivering the Promise of End-to-End Traceability Throughout the Subway System](#)

[► Inventory Management Solution Helps Eliminate Pain for More Than 24,000 Restaurants Across North America Using GS1 Standards](#)

Next Steps...Persevere!

1. Understand the details of FSMA 204:
 - Take advantage of fda.gov and **GS1 US Resources**
2. Get leadership support and secure team/budget
3. Collaborate with your trading partners
4. Evaluate current capabilities, systems and processes
5. Identify internal and external gaps with the **GS1 US Readiness Checklist**
6. You're not alone- we can help!
 - Visit us at gs1us.org/foodsafety
 - Email us at: foodsafety@gs1us.org





GS1 US Resources & Education



FREE

GS1 Standards for FSMA Rule 204 Microlearning ▶

Informational module on GS1 Standards that can help you prepare to meet the requirements.

FREE

Readiness Checklist for FSMA Rule 204 ▶

Understand who in your organization to involve, what steps are needed, and what resources are available.

FREE

Frequently Asked Questions on FSMA Rule 204 ▶

These FAQs provide an overview of the final Food Safety Modernization Act (FSMA), Section 204(d), and information on how GS1 Standards can help your company meet the requirements.

FREE

GS1 Standards for FSMA Rule 204 Guidance ▶

- Application of GS1 Standards for FSMA Rule 204 Guideline
- EDI Recommendations for FSMA Rule 204
- EPCIS Recommendations for FSMA Rule 204

FOR FEE

FSMA Rule 204 E-Learning Course ▶

For those **familiar with GS1 Standards**, this self-paced on-demand module walks you through an example of how a company uses GS1 Standards to help meet FSMA Rule 204 requirements.

FOR FEE

GS1 Standards for Traceability Certificate Course ▶

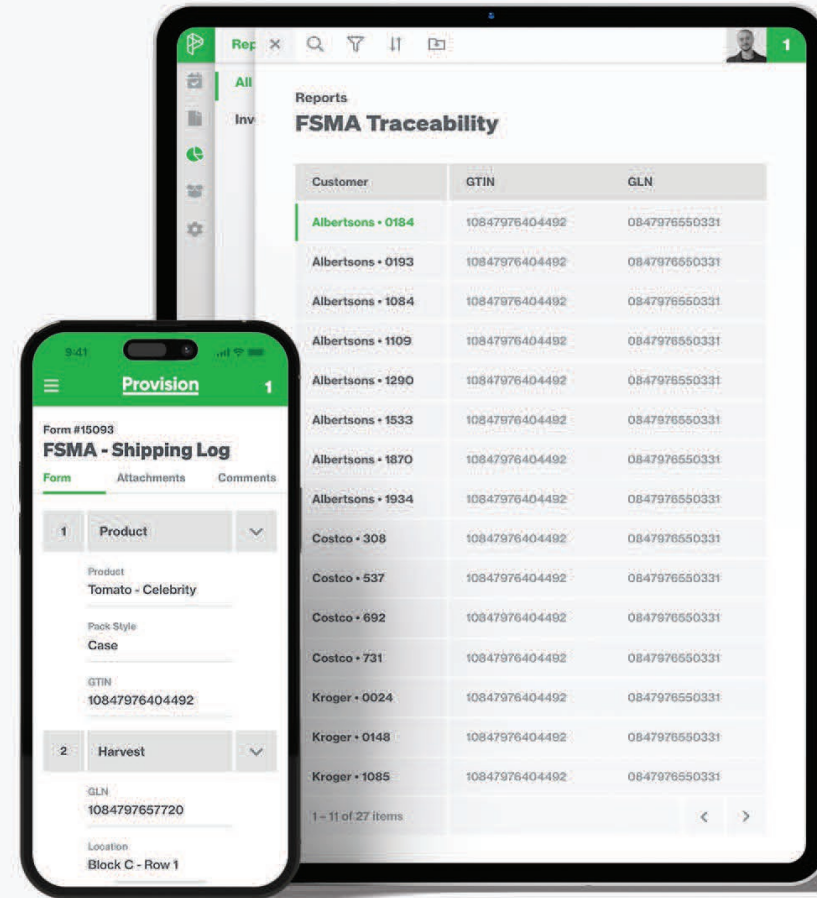
For those **new to GS1 Standards**, learn best practices for case-level traceability and how to implement them. Receive professional credential upon completion. *Bonus content included: FSMA Rule 204 & EPCIS e-Learning Module.*



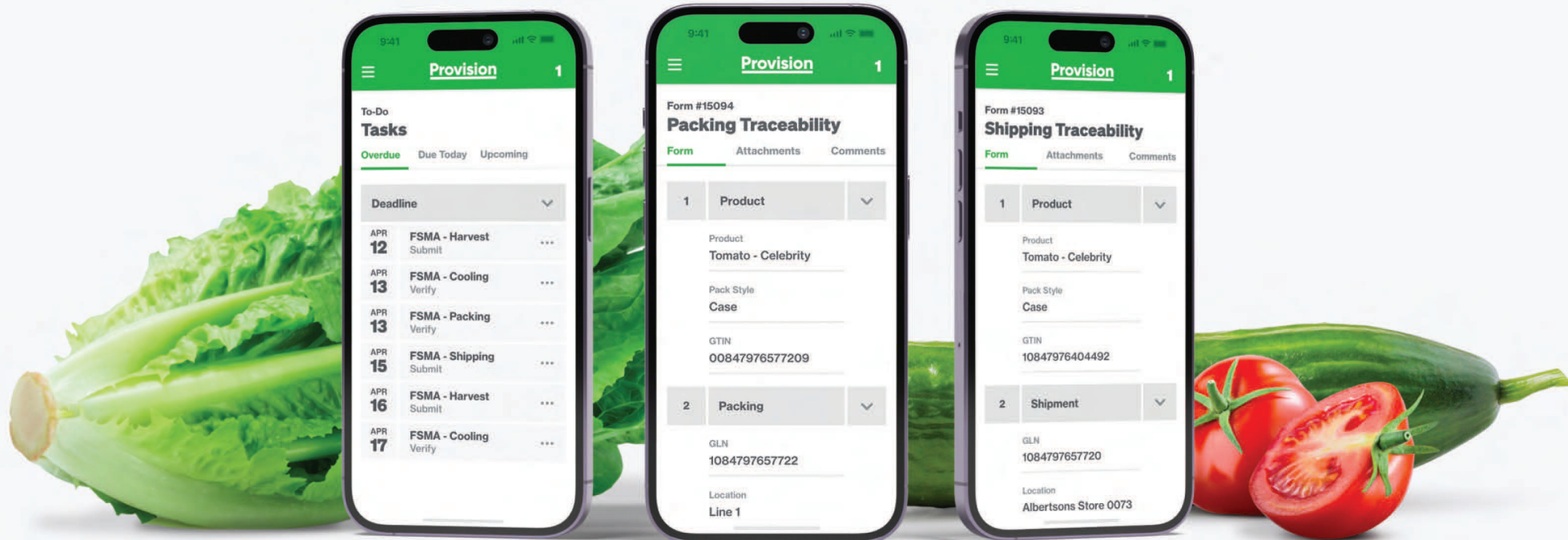
Provision

Smart Traceability

FSMA 204 Compliance
2025 Solution Guide



We build intuitive, flexible solutions for compliance.





The challenge with FSMA 204.

Vast amounts of data, harmonized internally and externally.



Data Standards

Lack of unified formats across the supply chain



Data Fragmentation

Information in many unintegrated systems



Data Entry

New digital records for non-technical staff



Time study on data entry.

At a single-site commissary kitchen with multi-ingredient products.



Receiving

3 staff required
If data entry is fully manual

20 Truckloads daily
26 Pallets per truckload
2.5 Mins per product



Transformation

2 staff required
If data entry is fully manual

83 Finished goods daily
6 Ingredients each
11 Mins per record



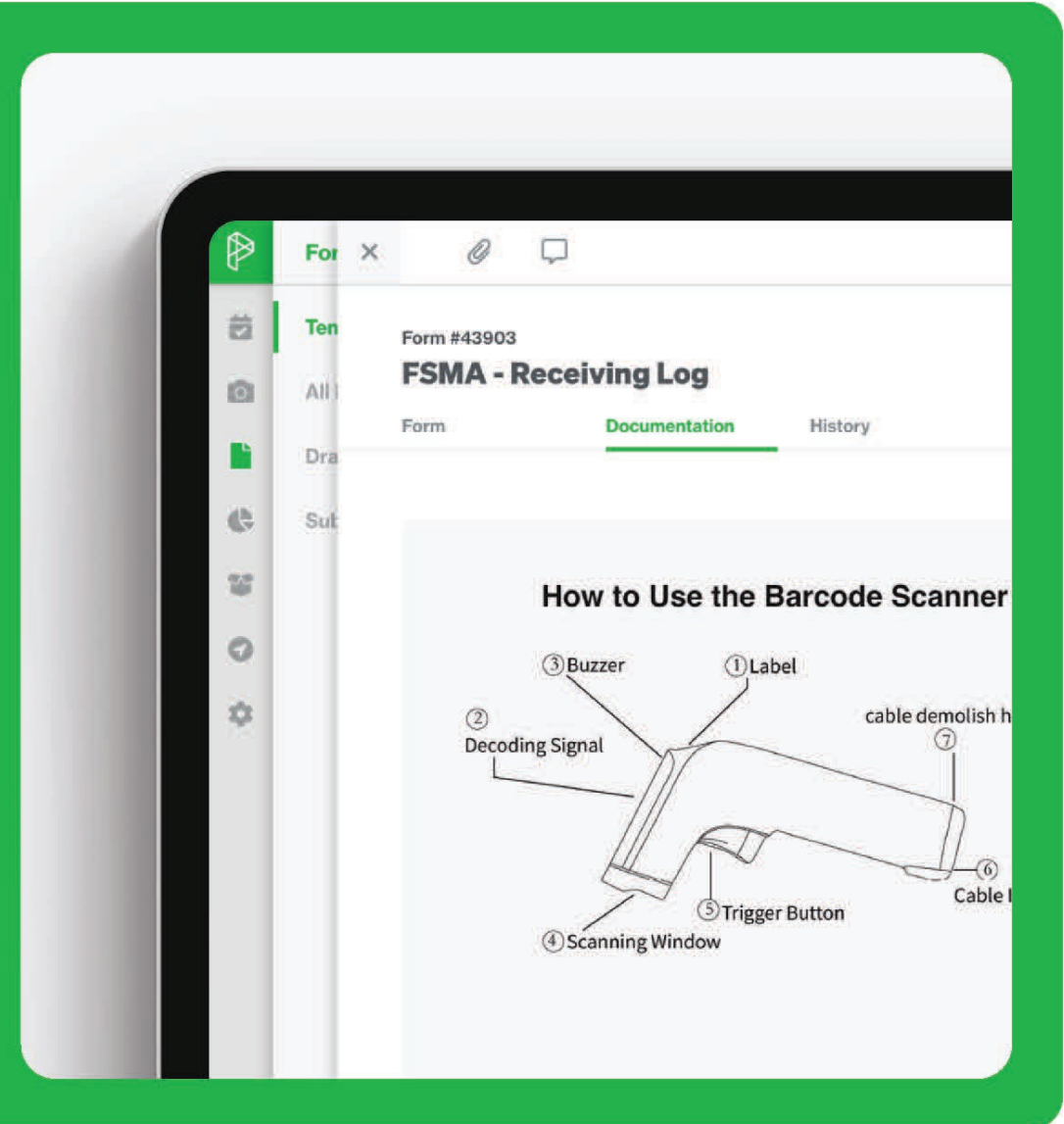
Shipping

3 staff required
If data entry is fully manual

90 Shipments daily
12 Mins per record

Part One

Efficiency





Objectives for data entry.

Beating the time study of manual record-keeping.



The Goal

You become FSMA 204 compliant without hiring new staff for record-keeping



The Blockers

A lack of automation and integration forces manual data entry.

Easily ingest traceability data.

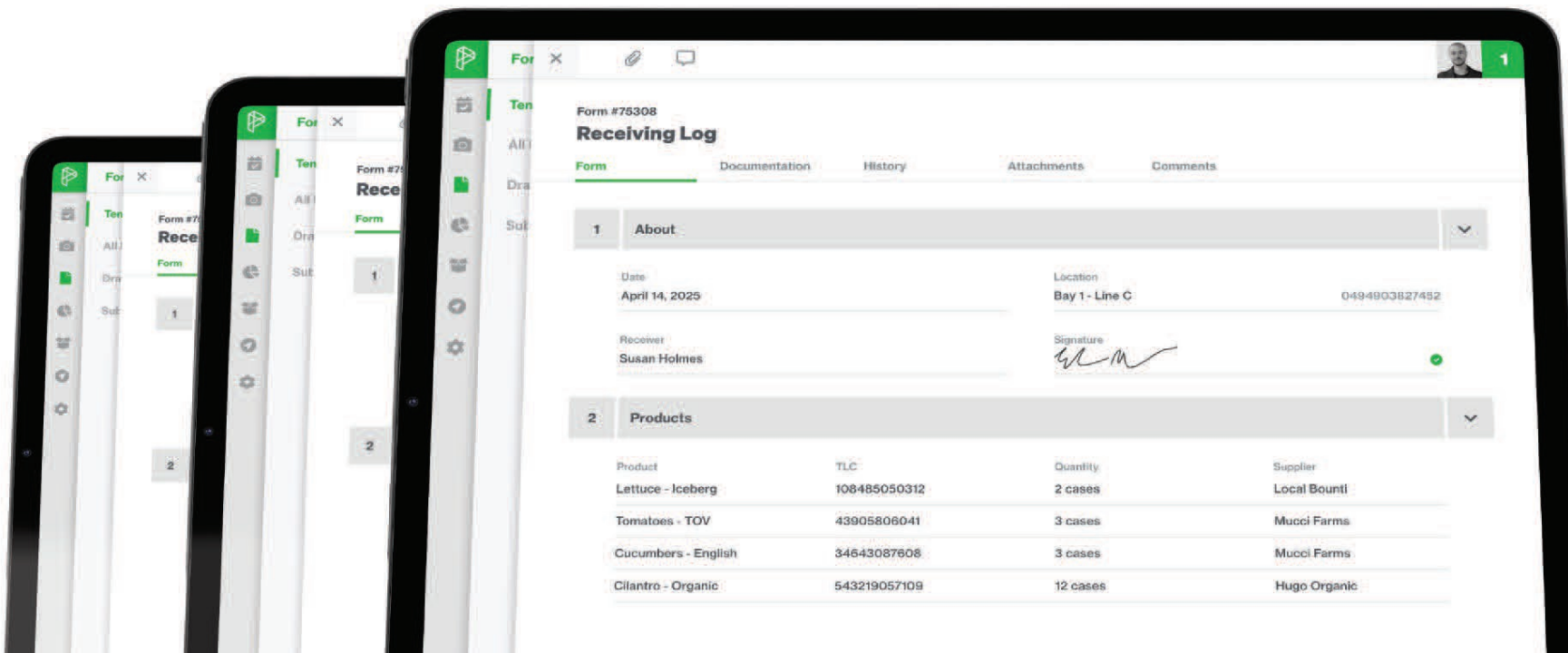
Accept advanced shipping notices from supplier networks.



Open API



EDI Plug-Ins



The image shows three tablets displaying the IDDBA Receiving Log interface. The main tablet in the foreground shows the 'Form #75308 Receiving Log' with tabs for 'Form', 'Documentation', 'History', 'Attachments', and 'Comments'. The 'Form' tab is active, showing a '1 About' section with fields for Date (April 14, 2025), Location (Bay 1 - Line C), Receiver (Susan Holmes), and a signature. Below this is a '2 Products' section with a table of received items.

Product	TLC	Quantity	Supplier
Lettuce - Iceberg	108485050312	2 cases	Local Bounti
Tomatoes - TOV	43905806041	3 cases	Mucci Farms
Cucumbers - English	34643087608	3 cases	Mucci Farms
Cilantro - Organic	543219057109	12 cases	Hugo Organic

Complete receiving records in seconds.

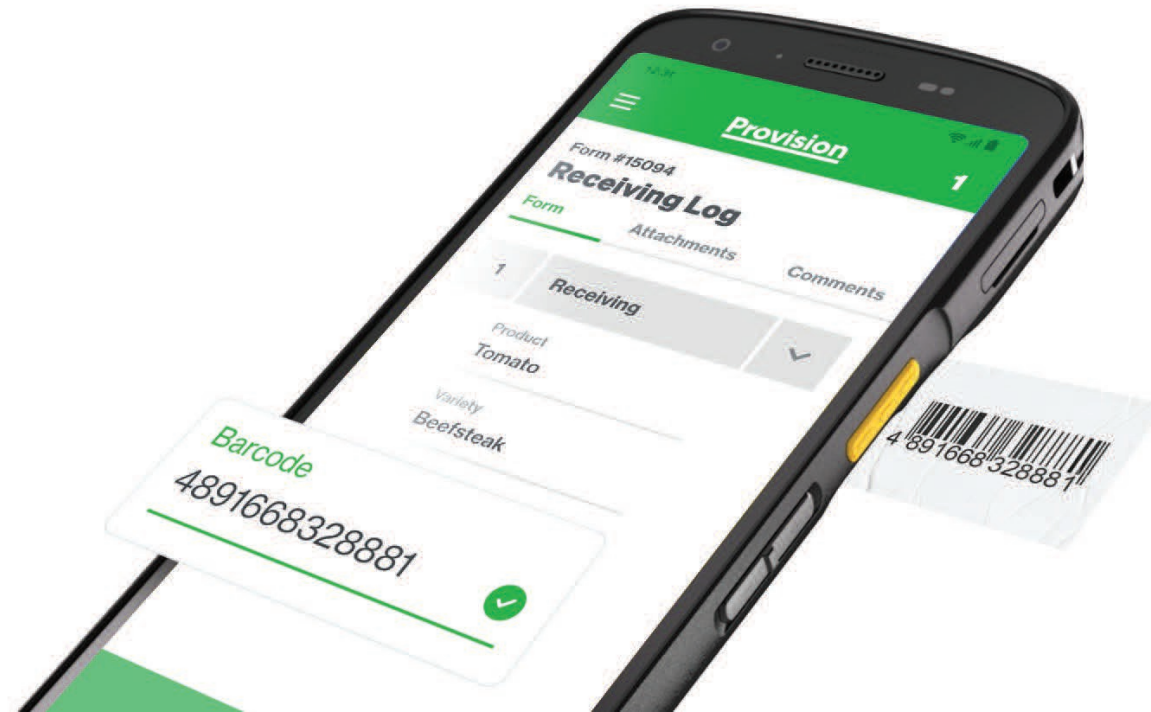
Save time and prevent errors by autofilling key data elements.



Scan data from GS1 labels



Import data from ASNs





Keep production running at full-pace.

Streamline transformation records with a configurable product library.



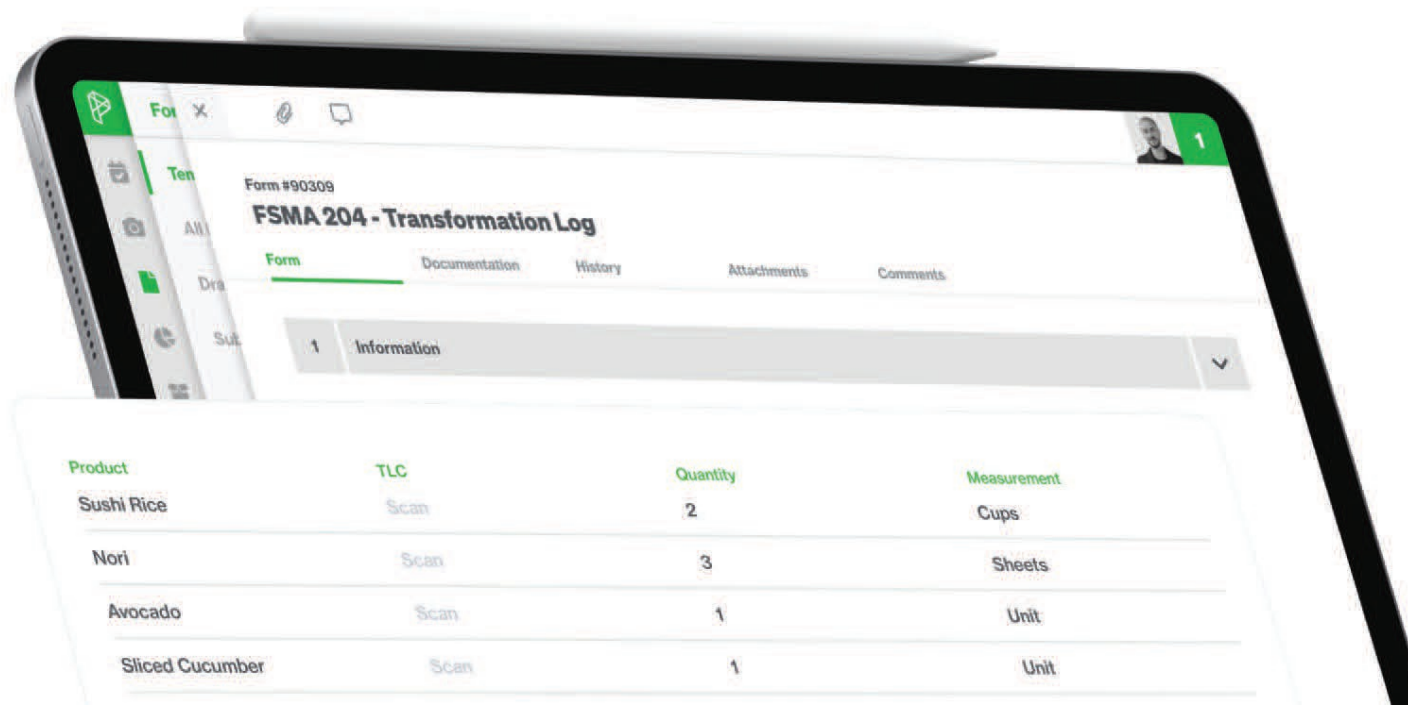
Autofill KDEs from receiving



Guided lot picking



Auto-calculate quantities



Complete traceability sequences in a snap.

Log shipments and export data with advanced notices.



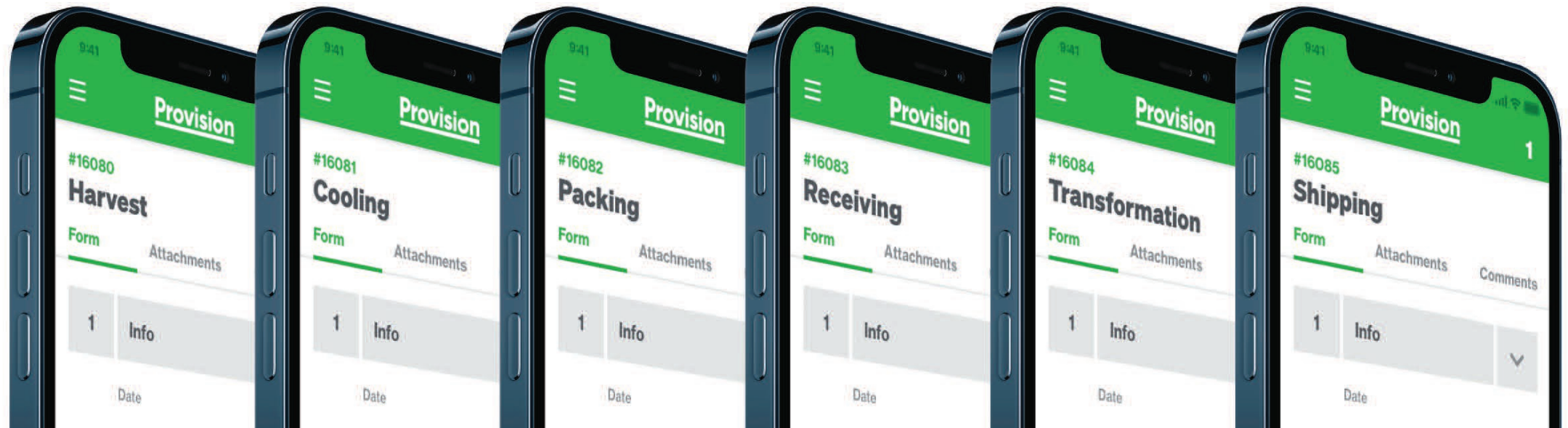
Autofill customer addresses



Connect record history

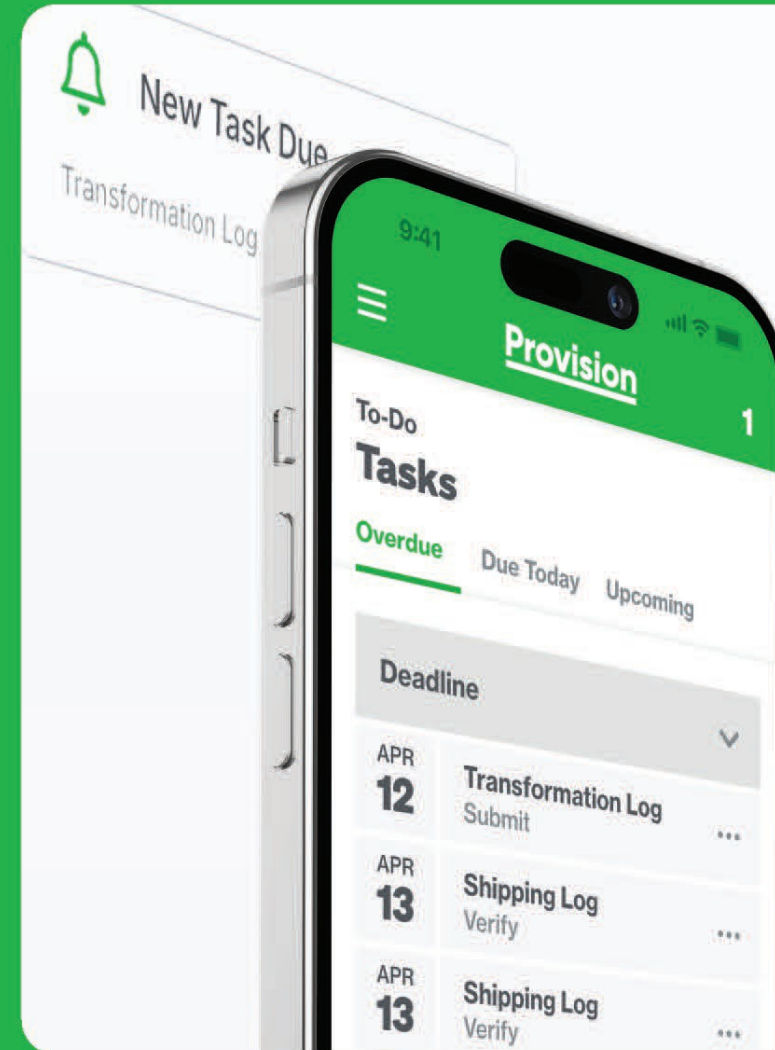


Share ASNs



Part Two

Compliance



Objectives for data **compliance.**

How to implement guardrails for non-technical operators.



The Goal

Staff enter compliant data without supervision or review



The Blockers

So many tasks and rules to remember, but so little time or familiarity

Guide operators in real-time.

Enable compliance among non-technical staff, without verbal reminders or manual review.



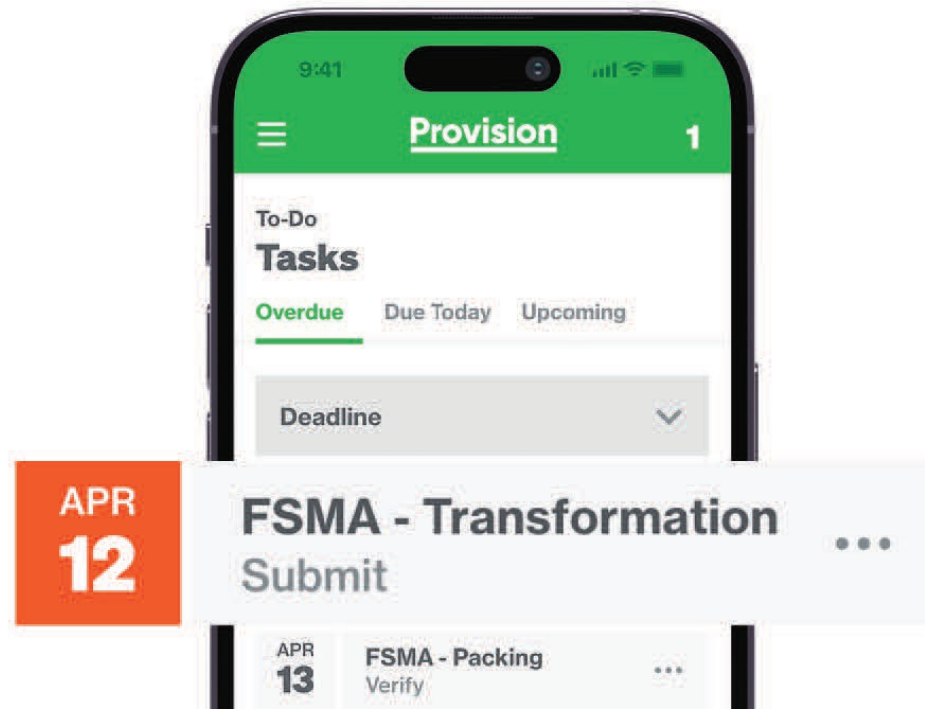
Task notifications



Live translation



Embedded SOPs



Objectives for data **reporting.**

How to make your traceback scalable and accessible.



The Goal

Managers can run a single search to fulfill an entire trace report



The Blockers

Different software used for different areas, without integration

Trace your history in seconds.

Easily isolate products and create a sortable spreadsheet.



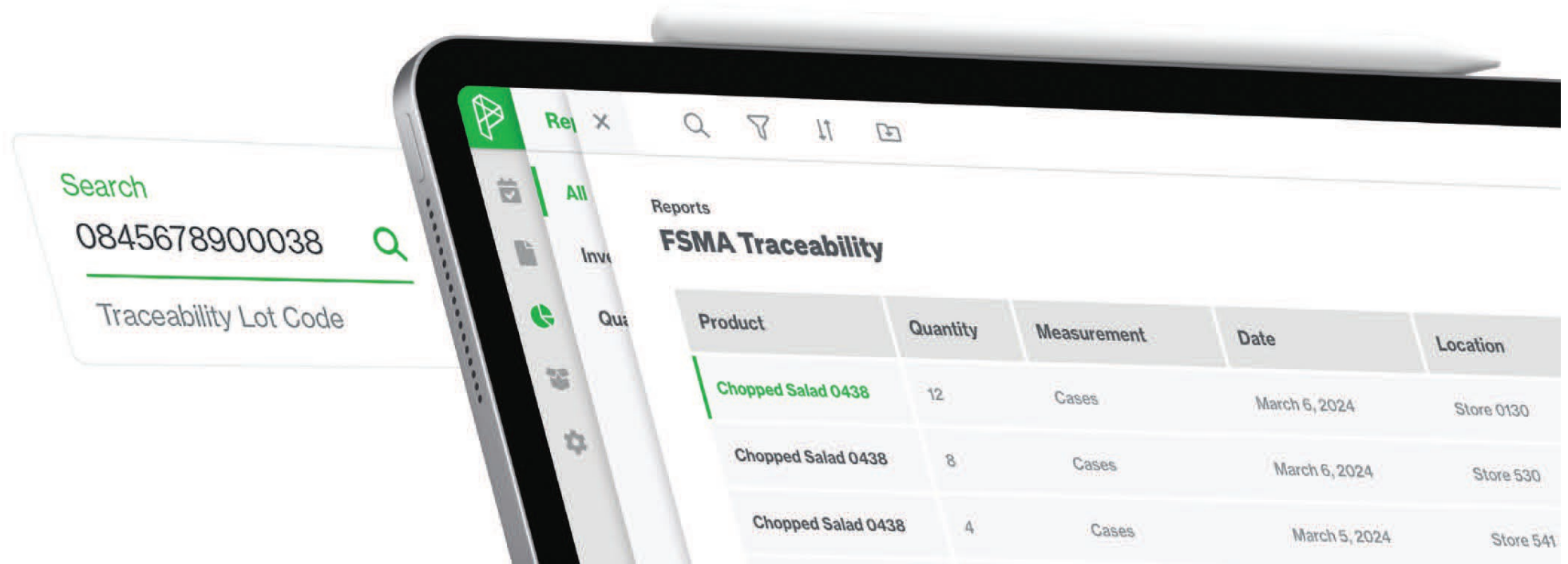
Unify all records



Search without I.T.



Export in one tap





Provision

provision.io

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