WHITE PAPER

From Compliance to Confidence: Preparing for FSMA 204 Food Traceability

A practical guide for produce growers, packers and distributors

In brief. The FDA's Food Traceability Rule asks covered companies to record the same set of facts at each step a food takes and to produce them quickly, in a sortable spreadsheet, when the FDA asks. This paper explains what the rule requires, why it is hard to meet with spreadsheets and paper, and how to build a traceability practice you can rehearse and trust.

JGE Innovative Software · Tucson, Arizona · jgesoftware.com
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1 Executive summary

Food traceability is no longer only a customer request. Section 204 of the Food Safety Modernization Act (FSMA) and the FDA's Food Traceability Rule require companies that handle foods on the Food Traceability List to keep specific records at specific points in the supply chain, and to give them to the FDA within 24 hours of a request. For a produce business the risk is practical, not theoretical: during an outbreak or recall, the company that can show where a lot came from and where it went, in hours rather than days, keeps customers, limits the size of a recall and protects its brand.

Most operations already collect much of this information. The difficulty is that it lives in different places (harvest sheets, packing-house systems, bills of lading, customer portals), in different formats, under lot codes that change or disappear between steps. This paper describes five principles for closing that gap and shows how Continuum Traceability, a web application from JGE Innovative Software, applies them.

Key points

- The rule is built on **Critical Tracking Events (CTEs)** and the **Key Data Elements (KDEs)** recorded at each one, tied together by a **traceability lot code**.
- Records must be available to the FDA within **24 hours**, with an **electronic sortable spreadsheet** when the FDA needs it for an outbreak, recall or other public health threat.
- The compliance date was extended to **July 20, 2028**, and Congress directed the FDA not to enforce the rule before then. The extra time is best spent on process and rehearsal, not postponement.
- The weak points are rarely the software. They are **lot codes lost at receiving**, **labels that cannot be scanned**, **corrections that overwrite history** and **reports nobody has tried to produce under time pressure**.
- A **mock recall**, run on your own data, is the most reliable test of readiness.

2 What the rule requires

The FDA's Food Traceability Rule (FSMA Section 204) applies to foods on the **Food Traceability List**, which includes many fresh fruits and vegetables, fresh-cut produce, sprouts, shell eggs, certain cheeses, nut butters and some seafood. Covered firms must keep traceability records for the events below and link them with a **traceability lot code (TLC)**.

Term	Meaning
Critical Tracking Event (CTE)	A step in the food's journey that must be recorded: harvesting, cooling, initial packing, first land-based receiving, shipping, receiving and transformation.
Key Data Element (KDE)	A fact recorded for an event: the food and its quantity and unit, the traceability lot code, where it came from and went, the dates, and a reference document.
Traceability lot code (TLC)	The code that identifies a lot. It is assigned at initial packing (or at first receiving, for some foods) and must be carried forward and linked at every later event.

Traceability lot code source	The location that assigned the lot code, recorded at receiving so a lot can be traced back to where its code was created.
Sortable spreadsheet	An electronic, sortable file of the relevant records that the FDA can ask for to respond to an outbreak, recall or other public health threat.

Covered firms must provide records, with the information needed to understand them, within 24 hours of a request. The FDA has extended the original January 20, 2026 compliance date by 30 months, to **July 20, 2028**, and Congress directed the agency not to enforce the rule before that date. Requirements differ by role and some operations are exempt, so each company should confirm how the rule applies to it.

3 Why it is hard in practice

Companies that try to meet the rule with spreadsheets and paper run into the same problems:

- **Fragmented records.** Harvest, cooling, packing, shipping and receiving are recorded in different tools by different people, so no one can answer "where did this lot go?" without a manual search.
- **Lost lot codes.** A lot code that is not on the case label, or is retyped at receiving, breaks the chain. Transformations (cutting, mixing, re-packing) make the chain harder still, because several lots become one.
- **Labels that do not scan.** Receivers need a barcode that carries the product (GTIN), lot and date in a standard format, or they re-key everything by hand.
- **Corrections that destroy history.** Deleting and retyping a wrong entry removes the evidence of what was first recorded, which is the opposite of what an auditor or the FDA expects.
- **Partner formats.** Customers and retail platforms ask for the same shipping data in their own layouts, and each hand-made export is another chance for error.
- **Untested reports.** A report that has never been produced under time pressure is an assumption, not a capability.

For a business with a Spanish-speaking workforce, a further obstacle is a tool that is only usable in English at the packing line or the receiving dock.

4 Five principles for a traceability practice

These principles do not depend on any particular product. They describe what a practice must do to survive a request for records.

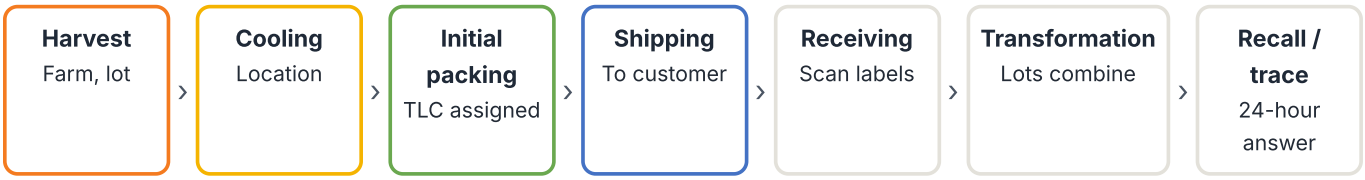
1. **Record at the point of work.** Data entered on the packing line or at the dock, by the person doing the work, is more accurate than data re-typed later from paper.
2. **Put the lot on the label in a standard code.** GS1 barcodes that carry the GTIN, lot and date let the next company scan instead of type.
3. **Keep lineage, not just events.** The system must connect a finished lot to the lots it came from and to the customers who received it, in both directions.
4. **Correct by voiding, not by deleting.** Mistakes happen. The record of the mistake, who corrected it, when

and why, should stay.

5 **Rehearse.** Run a mock recall on your own data and measure how long it takes. Fix what slows you down.

5 How Continuum Traceability puts this into practice

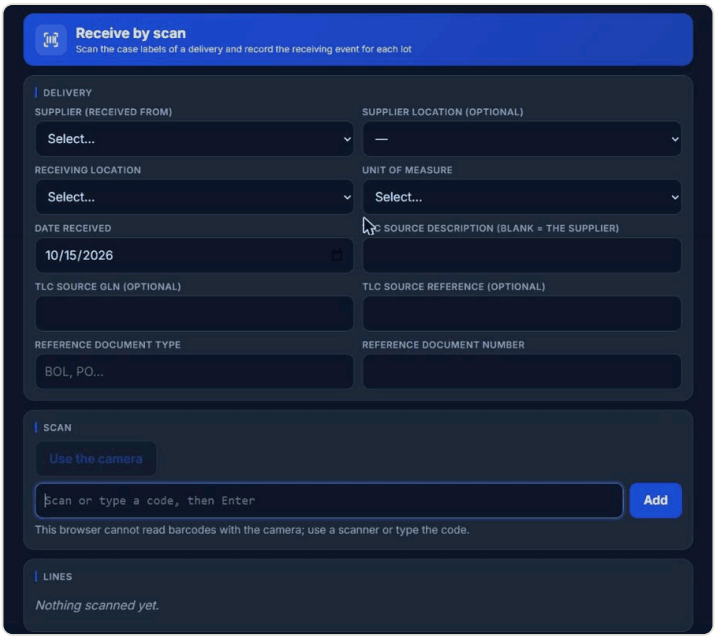
Continuum Traceability is a web application that records CTEs and KDEs, prints GS1-compliant carton and pallet labels, and produces the reports regulators and trading partners ask for. It is used from any modern browser, with screens in English and Spanish chosen per user.



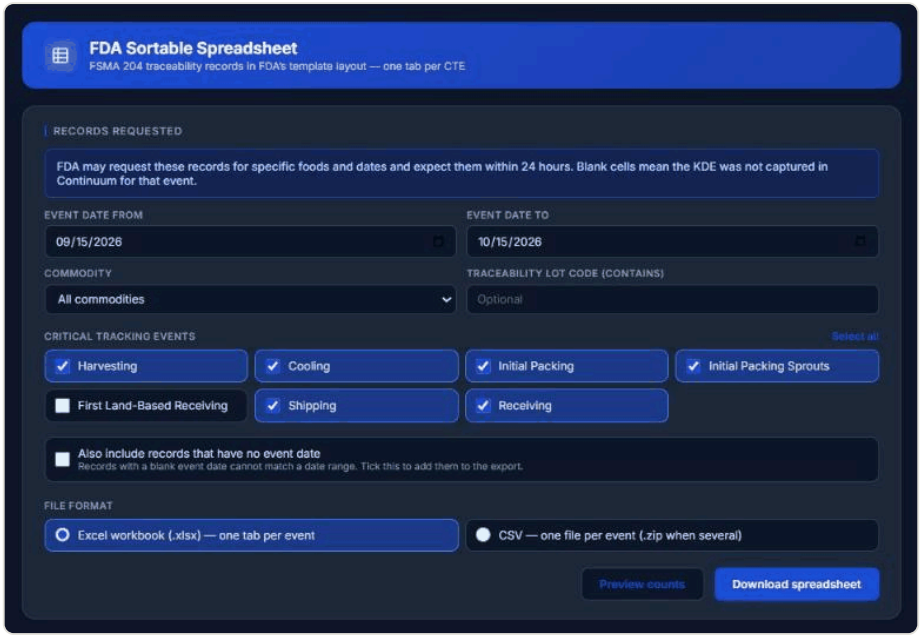
The events the application records, from harvest to a trace or recall.

What you need	What the application provides
Record each CTE with its KDEs	Entry forms for harvesting, cooling, initial packing (including sprouts), shipping, receiving and transformation, with the data elements required for each event. A transformation of raw produce that was never packed carries its harvest data instead of a lot code, and a fishing-vessel event is kept as a catch record.
Standard labels	GS1-128 carton and pallet labels printed as PDF, ZPL or directly to a thermal printer through Print Bridge, with reprint from the document serial number.
Keep the lot code on receipt	Receive by scan: scan the labels on a delivery and the product, lot and date are read from the barcode, one receiving document per lot.
Bring in existing data	CSV import for harvest and receiving events, with every row checked before anything is saved.
Keep exemption records	Where an exemption depends on paperwork, keep it with the traceability records: annual written assurances, kill-step records and written agreements with their 3-year renewal, with reminders, and the processing disclosure printed on shipping documents.
Correct without erasing	Void or correct a document with a reason; the document stays on record marked void, leaves every trace and report, and can be re-entered corrected. Dependent shipments are shown before you decide.
Trace in both directions	Trace report with one step back and one step forward, and a public trace page that each label's QR code opens.
Recall	Create a recall by source and dates or by lot code, optionally including every lot made from the recalled lots, with a printable list of customers to notify.
Answer the FDA	The FDA sortable spreadsheet, one tab per CTE, filtered by date, product and lot code.
Serve trading partners	Shipping KDEs prepared for ReposiTrak by direct upload or as a file in FDA shipping format.

Control who can do what	Page-level permissions per user, company administrators, password rules and automatic sign-out.
Connect other systems	A JSON API with bearer tokens for reading events, lot lineage and labels, and for importing harvest and receiving events.



Receive by scan: the delivery details, the scan box and the lines read from the labels.



The FDA sortable spreadsheet: choose dates, product, lot code and the events to include.

6 Proving readiness: the mock recall

A mock recall is a rehearsal. Pick a lot that has already shipped and ask the question an investigator would ask. Then time the answer.

1. Choose a finished lot and write down its lot code and the time you start.
2. Trace it back: find the harvest or receiving events and the source of each contributing lot.
3. Trace it forward: list every customer that received the lot or anything made from it, with quantities and dates.
4. Create the recall by lot code, including lots made from the recalled lot, and print the customer list.
5. Produce the FDA sortable spreadsheet for the date range and lot.
6. Record the elapsed time, every gap you found (missing lot code, unknown customer, mismatched quantity) and who will fix each one.

Repeat the exercise after each fix and again whenever the operation changes. The goal is not a perfect first run. It is a short, repeatable one, well inside the 24-hour window.

7 A practical roadmap

The extended compliance date gives time to do this properly. A sequence that works for most operations:

Phase	Actions
Weeks 1 to 2: Set up	Load products, packaging, sources, destinations and locations. Decide who enters what, and set each user's permissions and language.
Weeks 3 to 6: Pilot	Run one commodity or one packing line end to end: record events, print labels, receive by scan at one customer or supplier.
Weeks 7 to 10: Rehearse	Run a mock recall on pilot lots. Fix gaps in lot codes, quantities and partner data. Train the rest of the team.
Ongoing: Operate	Roll out to all lines and locations, connect trading partners, review the reports regularly and repeat the mock recall at least once a year.

8 Conclusion

The Food Traceability Rule asks for something simple to state and demanding to do: the same facts, at every step, retrievable in a day. Meeting it is mostly a matter of discipline in how data is captured and how mistakes are handled, supported by software that makes the disciplined way the easy way. Companies that use the extra time to build that discipline and to rehearse will find that the rule is a smaller step than it first appears, and that the same records also speed up routine questions from customers and auditors.

About JGE Innovative Software

JGE Innovative Software, based in Tucson, Arizona, builds web applications for the fresh produce industry: quality-control inspections, food safety management, pest control and traceability. To see Continuum Traceability on your own data or to run a mock recall with your team, visit **jgesoftware.com** and use the contact form.

Sources

1. U.S. Food and Drug Administration, FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods (fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods).
2. U.S. Food and Drug Administration, Food Traceability List (fda.gov).
3. JGE Innovative Software, Continuum Traceability User Manual and Administrator Guide, October 2026.

This paper is general information, not legal advice. The Food Traceability Rule has exemptions and role-specific requirements; confirm how it applies to your company with qualified counsel or your regulator. Product capabilities described are those of Continuum Traceability as of October 2026.