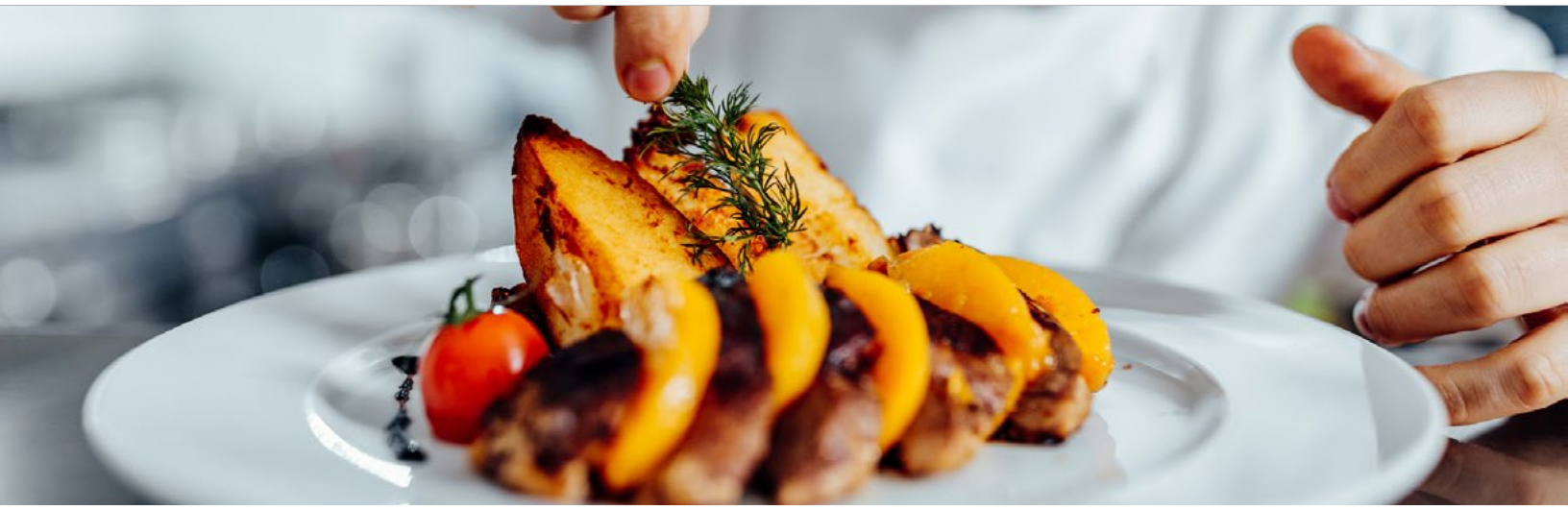
One Network Enterprises™

# Effective and Safe Food Management on the NEO Platform

## Meeting and Exceeding the FDA and Recall Requirements for Food Traceability and FSMA 204

By Joe Bellini, EVP, One Network Enterprises



**Traceability is a core capability required for understanding the movement of goods across a supply chain network. It is also an enabling capability that powers product authentication, network efficiency, consumer transparency, and product recalls.**

The FDA's proposed **FSMA 204** rule establishes requirements for end-to-end food traceability. This is an expansion of today's practice of "one-up, one-back" traceability, commonly referred to as a hub and spoke supply chain structure.

Traditional system architectures are designed to support hub and spoke given that they were designed primarily for the enterprise with the ability to buy from a supplier and sell to a customer, "one-up, one-back."

However, enabling end-to-end food traceability across each step (as required for 204), along with the actionability required to execute a recall requires the capabilities of a network platform. One Network's **NEO Platform** has proven, end-to end, track and trace capabilities in the platform. ONE has successfully deployed Chain of Custody and traceability in multiple sectors including food, pharmaceutical, and high tech.

The food industry is evolving, and thus in order to stay competitive, the processes, technologies, and trading partner ecosystem must evolve with it. Advanced supply chain network platforms and analytics, along with effective and efficient onboarding of trading partners and their data, will be a critical part of the evolution required to meet the critical tracking events and key data elements as required by FSMA 204.

Whether you operate in food retailing, food distribution, or both, you need to understand what your overall supply chain looks like and the role you play in complying under 204. If your current capabilities, as is likely, are limited to some level of "one up, one back" data interaction, and for a few, some level of logistics visibility, a platform upgrade will be required.

The good news is that One Network's NEO Platform layers in on top of existing legacy systems, so complying with 204 doesn't require a "rip and replace." Then it is a simple matter enable the critical capabilities to fulfill the requirement to capture and store data for two years and the to produce data within 24 hours in the event of a recall.

## WHAT DOES SECTION 204 COVER?

Section 204 applies to those who process, pack or hold foods on the food traceability list (FTL), which includes foods and ingredients that will need additional record-keeping. Critical tracking events may take place at any part in the supply chain that involves the growing, receiving, transforming, creating or shipping of food.

Examples of food items in the proposed rule to be approved in November, effective in January, and fully implemented by 2025 include items like leafy greens, fresh fruits and vegetables as expected along with nut butters, soft cheeses, fresh herbs, peppers, melons, shell eggs and a number of seafood items.

Traceability in FSMA 204 essentially replaces the method that many producers and distributors have used of tracing "one-up

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and one-back" within the supply chain. Supply chains have increased in complexity with omni channel demand, smaller lot sizes, global sourcing, increased mix, and assortment availability. Traditional technologies have made it much more challenging for government agencies, producers, and distributors to trace issues across these more complex supply chain networks.

Sites that hold, pack, manufacture, or processes foods listed on the FTL must keep records of any Key Data Elements (KDEs) resulting from Critical Tracking Events (CTEs).

## HOW ONE NETWORK SUPPORTS FSMA

One Network's NEO Platform provides full end-to-end network visibility, as well as, planning, actionability, tracking, and transaction execution across the network. This is enabled by a network-wide common data model and master data management infrastructure. Gaps in current systems in complying with 204, can be filled by layering the network on top of existing legacy systems, and interoperating with them. Any gaps in existing functionality can then be eliminated by activating network services, which are deep and robust across demand, supply, logistics, and fulfillment.

Customers, distributors, copackers, producers, suppliers and carriers are onboarded in the network as hubs as part of a fast and efficient process, many parts of which are automated. The pathways created by a hub-to-hub trading partner ecosystem are exactly what is required by 204, as opposed to the old "one-up, one-back" hub and spoke model. In the case of an investigation or recall, this hub-to-hub architecture enables on-demand trace-back and trace-forward down to the lot level.

While only those who deal with foods on the list are mandated, the FDA is encouraging others to adopt the same traceability processes. The desired outcome is to create a capability that drives real-time responsiveness through tracebacks and recalls across the network, which will minimize risk, ensure enhanced food safety, and better health outcomes. And not only does this capability generate improved health outcomes, but it is also more cost effective at the same time.

Digitizing supply chains networks to drive effectiveness and efficiency increases the data volume requirement along with the need for advanced analytics and automation to make the data and related decision making actionable. Compliance with 204 certainly falls within this construct given the need to track the sheer volume of data required by the new traceability rules.

For example, a facility must keep Key Data Elements (KDE) for each Critical Tracking Event (CTE) and of course have the ability to model the CTE's with an advanced network traceability and tracking capability.

A site must create KDEs for each of the CTEs, including growing, receiving, creating, transforming and shipping. Due to the fact that the automation of KDE collection is paramount to more efficient traceability compliance, the network must enable automated and dynamic workflow across roles and trading partners.

To ensure compliance with FMSA 204, organizations and their respective sites and operations will have to maintain traceability program records for regulators. The ability to respond quickly is an important goal of FSMA 204, and facilities will have to respond within 24 hours to the FDA's request for traceability records. The requirement is to deliver an electronic spreadsheet to the FDA within 24 hours when the FDA is investigating a public health threat or outbreak.

The NEO Platform is the next generation food management software platform, built on a real-time, single version of the truth, that enables compliance with 204, along with the likely expansion of the food list and traceability requirements in the coming years.

Based on your role and position in the supply chain network you must now track what you made and who you shipped it to; as well as track what you received and who you shipped it to, as part of the end-to-end process around food safety.

Roles will vary in the network given a processor could be considered both a receiver and a transformer since they take physical possession of product from a grower or supplier and they also cut, repack, or otherwise transform the product.

The FDA has also created a distinct role known as first receiver. A first receiver is defined as "the first person (other than a farm) who purchases and takes physical possession of a listed food." The FDA clarifies that the first receiver role is designed to accommodate on-farm activities where product may be moved but not sold (e.g. sent to a cooler on the farm).

**One Network is designed as a role-based system thus easily accommodates these types of requirements.**

The NEO Platform generates a reference record which is used to identify events in food supply chain, such as a shipping, receiving, growing, creating, or transformation events and data, including bills of lading, purchase orders, advance shipping notices, work orders, invoices, batch logs, production logs, and receipts.

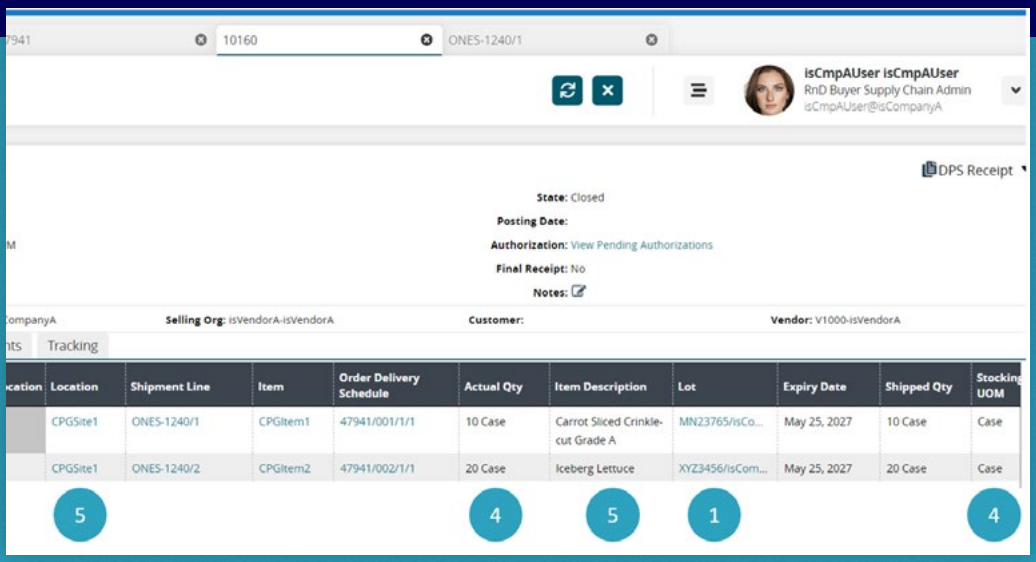
The platform supports all varieties of data related to traceability, including: traceability lot codes, traceability product descriptions (including the category code or term), category name, and trade description; single ingredient products including the brand name, commodity, variety, packaging size, and packaging style; and multiple ingredient products including the brand name, product name, packaging size, and packaging style.

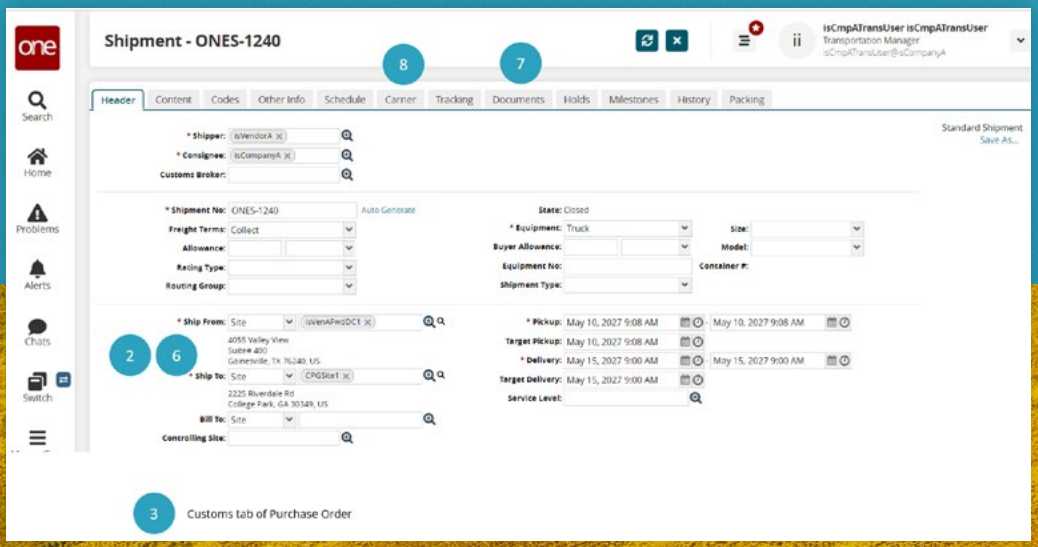
As part of 204, if you apply a "kill-step," the requirements do not apply to your subsequent shipping of the product; or if you receive a food that has been subject to a kill step, the requirements do not apply to your receipt or subsequent transformation and/or shipping of food. However, simply digitizing your supply chain network is driving significant value around revenues, expense, and cost, across all trading partners, and complying with 204 is just one of the many benefits companies will receive.

The following One Network screenshots provide a description of reference records in which you generate and maintain required 204 information. The drill downs available on

**FSMA 204**

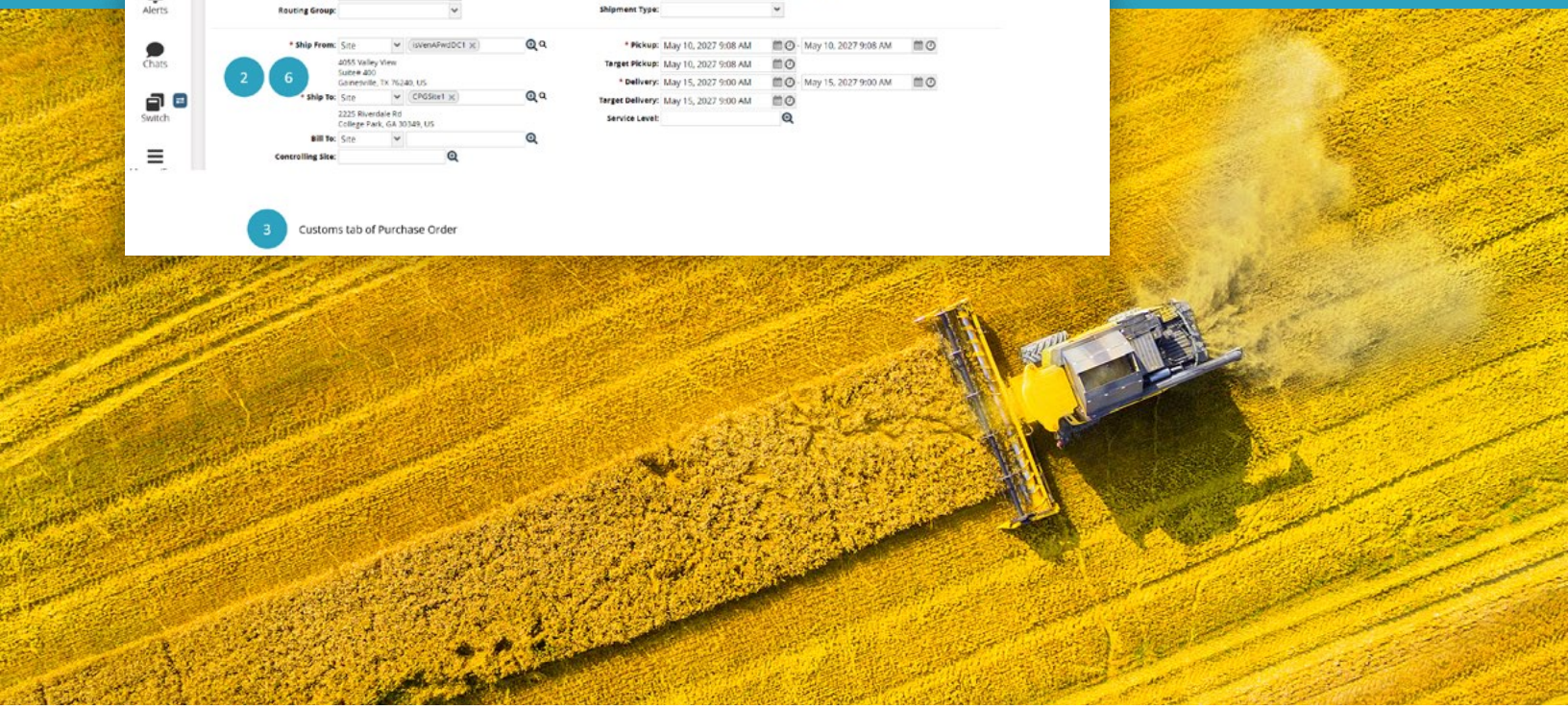
- First Receiver (first person who purchases and takes possession)
- ONE Network to KDE Mapping



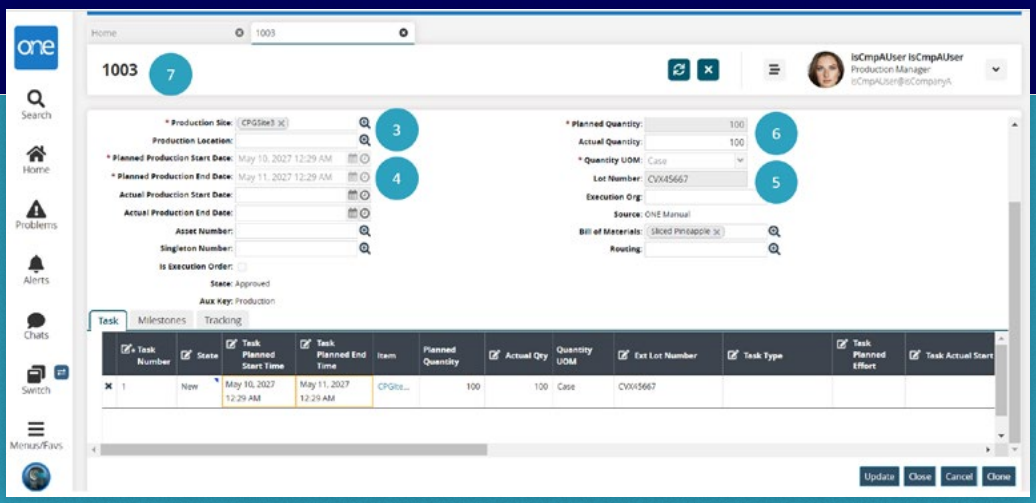

**FIRST RECEIVER'S KDE**

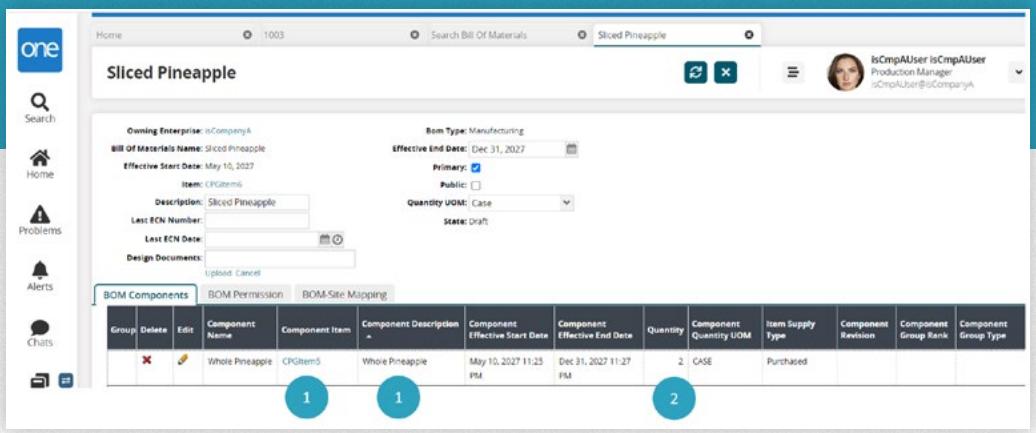
1. Traceability Lot Code
2. Location Identifier & Location Description of Source
3. Entry Number (If imported)
4. Quantity and Unit of Measure
5. Traceability Identifier and Description
6. Location Identifier, location description and point of contact for traceability lot code generator
7. Reference Records (Invoice, BoL, etc)
8. Name of the Transporter



**FSMA 204 Transformation**

- Transformation (combining ingredients or processing)
- ONE Network to KDE Mapping




**TRANSFORMATION KDE's**

1. Item Identifier & Description of ingredients used
2. Quantity of each traceable ingredient used
3. Location Identifier and Description of where transformation occurred
4. Date of Transformation
5. New Traceability Lot Identifier and Description
6. Quantity and Unit of Measure for New Item Produced
7. Reference Record Types and Numbers for records related to transformation

these fields demonstrate where on the records the required information appears, and a workflow as to how reference records are linked.

You can generate a list of foods on the Food Traceability List that you ship, including the traceability product identifier and traceability product description. The workflow also demonstrates how you establish and assign traceability lot codes to foods on the Food Traceability List, and is extended for any other information needed to understand the data provided in any records, for example coding systems, glossaries, or abbreviations.

## MASTER DATA MANAGEMENT

End-to-end master data management is a core enabling capability for the KDE's. The platform is designed to gather data through system integration, configurable UIs, or bulk uploads. The data is cleansed and enriched with configurable business rules which can easily be applied to the KDE requirements.

Given the importance of this data, review and approval for centralized administration is designed in as part of the process, along with full collaboration across trading partners. Data from both suppliers and customers can be

updated based on automated processes, a workbench-based interactive process, or through the AI-based NEO Databots.

Food traceability and recall data requirements are fully captured and enabled across the network and presented on various dashboards or interactive workbench UI's, such as Chain of Custody.

## DELIVER FRESH AND SAFE FOOD FOR LESS

With One Network you will be fully compliant with FSMA 204. You will enable a supply chain network solution across trading partners that delivers higher customer service levels at lower costs. And in the event of a recall, you will be able to pinpoint affected product, make a targeted and rapid recall, and resupply the impacted locations to minimize the negative effects on customers.

You will leverage a large network of over 100,000 suppliers and carriers giving you freedom from having to track down suppliers and requesting information and documents as recalls continue to impact operations.

**JOE BELLINI**

Joe has worked in multiple industry sectors including food retailing, foodservice, hi-tech, healthcare, automotive, and A&D. Joe is certified in AI/ML from MIT Sloan, is an alumnus of Harvard Business School, and holds degrees in Applied Mathematics and Statistics and Mechanical Engineering. He is a past award winner in the Mathematics Olympiad competition, authored the patent for Extended Enterprise Planning across a Supply Chain, and has been listed by Supply and Demand Chain Executive Magazine as a Pro to Know for the past two years.

## ABOUT ONE NETWORK

One Network is the leader in intelligent control towers for autonomous supply chain management. From inbound supply to outbound order fulfilment and logistics, this multi-tier, multiparty digital platform helps optimize and automate planning and execution across the entire Digital Supply Chain™ network and every trading partner. Powered by NEO, One Network's machine learning and intelligent agent technology, real time predictive and prescriptive analytics enable industry-leading performance for the highest services levels and product quality at the lowest possible cost. It's the industry's only solution with a fully integrated data model from the consumer to suppliers and all logistics partners, providing a network-wide, real-time single version of the truth. Leading global organizations have joined One Network, transforming industries like Retail, Food Service, Consumer Goods, Automotive, Healthcare, Public Sector, Telecom, Defense, and Logistics. Headquartered in Dallas, One Network has offices across the Americas, Europe, and APAC. For more information visit www.onenetwork.com

One Network Enterprises™

**US Corporate Headquarters**

4055 Valley View Ln, Suite 1000
Dallas, TX 75244

+1 866 302 1936 (toll free)
+1 972 385 8630
inquiries@onenetwork.com
www.onenetwork.com

**One Network Europe**

Office 3.03
1 King Street
London, EC2V 8AU

+44 (0) 203 28 66 901
europe@onenetwork.com

**One Network Australia/ Asia-Pacific/Japan**

+61 401 990 435
cedwards@onenetwork.com

**One Network India Pvt Ltd**

Westend Centre III, Survey No. 169/1,
Second Floor, South Wing, Sector 2
Aundh, Pune 411007, Maharashtra, India

+91 20 49111800
indiasales@onenetwork.com