Compliance with FSMA Rule 204

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Introduction

Are you a farmer, packager, processor, distributor, or retailer of foods such as lettuces and tomatoes? If so, then you need to comply with the Food Safety Modernization Act, Role 204 by January 2026.

Rule 204 relates to supply chain traceability. It requires that organizations must capture data that track specific events in a food's "farm-to-fork" journey, from harvesting/packing, shipping, receiving, processing/manufacturing, and distribution to the retailer or restaurant, and finally, to the consumer.

To paraphrase FMSA Rule 204: Entities that manufacture, process, pack, or hold foods on the Food Traceability List (FTL) must maintain records containing KDEs (Key Data Elements) associated with specific Critical Tracking Events (CTEs). These entities must provide food traceability information to the FDA within 24 hours, upon request. For details of the FTL, KDEs and CTEs, please see Appendix A to this paper.

While the guidance from the FDA, as to how to comply with rule 204, contains enough bureaucratic complexity to put anyone to sleep while reading it, this is essentially how the system functions now; but with more materials tracking and traceability data that needs to captured, especially relative to materials sourcing and transformation events. Here the big change is that the data needs to be captured and stored electronically rather than simply maintained in the form of paper records.

The big change, with the most impact, is that FSMA 204 requires sharing information between partners up and down the supply chain. These include details about where the materials were sourced from, what the lot numbers for their containers were, how they were transformed or repacked into new containers and what these lot numbers are, and who they were shipped to.

The concept is that, in the event of a food contamination outbreak or bioterrorism act, the FDA can go to an organization and get a complete picture of the supply-chain origin of all food products they have shipped, without needing to go to all the precursor organizations to get all the data they need to order a recall, without the multi-day delays, and resultant possible deaths, inherent in this process.

While highly beneficial, this does require a level of technical expertise in electronic data capture, barcode labeling, and especially distributed network computing and data exchange over

unreliable networks (which our Internet has become) that is extremely challenging for smaller, family-owned enterprises in our food supply chain.

This white-paper explores how smaller organizations, such as farmers, repackers, food processors, and distributors, can comply with FMSA rule 204 and what their options are.

A Simple Example

You run a small "ghost" kitchen (not associated with a restaurant) named "Sandwiches Wholesale" that makes packaged chicken, lettuce and tomato sandwiches which are primarily sold in gas stations, along with coffee, to their patrons. But you also supply boxes of these sandwiches to the local retail grocery stores, which are part of a major chain.

Distribution of sandwiches to the gas stations is handled by your cousin Jose who delivers these to the gas stations in his van. Sandwiches for the major retail chain are shipped by the pallet load using a 3PL refrigerated carrier to the local DC (distribution center) for the chain.

The bread and pre-cooked chicken, for your sandwiches get delivered daily by Sysco. Your lettuce comes by the box from Village Farms, where it is grown locally, and your tomatoes come from E. Armata Inc, which is a wholesaler of tomatoes.

As well as suppling product, everyone in this farm-to-fork supply chain is required capture and provide data about these products to their customers who are referred to by the FDA as downstream supply-chain trading partners:

1. The lettuce growing farmer – sells boxes of lettuce – which are on the FTL (Food Traceability List):
    a. Record which field, each box of lettuce was grown in
    b. Record who the boxes were shipped to
    c. Provide each recipient with the harvesting information
2. Sysco – supplies bread and chicken - not on the FTL
    a. Record the source of the bread and chicken
    b. Records any internal processing or repackaging
    c. Records what was delivered to who
    d. Provides lot and expiration date information on each package
    e. May provide lot and expiration date for each box or pallet of produce.
3. E. Armata – supplies boxes of tomato – on the FTL
    a. Records harvesting information for each batch of tomatoes
    b. Records into which boxes box of tomatoes each batch
    c. Records who boxes were shipped to

d. Provides harvesting information for each box of tomatoes

4. Wholesale Sandwiches – makes the chicken, lettuce and tomato sandwiches.
    a. Record who they received each box of lettuce and tomatoes from, including grower and harvesting information.
    b. Record who they received each box of bread and chicken from, including the manufacturer, distributor, lot number and expiration date.
    c. When making a batch of sandwiches, record the lot numbers of the materials used, as well as the boxes into which they went.
    d. Record who the boxes of sandwiches were shipped to – in this case, each gas station, and the DC for the retail chain.
    e. Provide the gas stations and the DC, the information about the boxes of sandwiches you shipped to them, what went into those sandwiches, their lot numbers and expiration dates, and when they were shipped or delivered.

In the food supply chain, we have a mix of large, tech-savvy organizations and small organization with no technology support at all. These organizations are now all required to exchange information, such that the FDA can go to any point in the supply chain and get the information they need to quickly deduce the possible source of contamination.

This information capture and data exchange is already being done by larger organizations but presents a major technical challenge for small and mid-size organizations in the food supply chain, many of whom are family owned, which is why we wrote this paper.

Barcode Labeling

If we examine the above list of requirements, we see that basically we are tracking boxes of product and the data related to their contents. To capture this data, we attached a unique tracking barcode to each box, scan the barcode and record the relevant information in a database.

Then, when we ship each box to its recipient, we also send the data (typically over the Internet), which the recipient stores in their own database. The recipient can then scan the tracking barcode and retrieve all the relevant information about the contents of the box or other container to which the tracking barcode was attached.

Each tracking barcode on each box, needs to be unique because different products, in different boxes, even though nominally the same, may have different lot number and expiration dates, and may have been harvested in different places or processed in different processing plants. As we live in a global economy, this applies to millions of different products in billions of different containers, making the generation of unique labels challenging.

Fortunately, this problem has been solved by the Global Standards One (GS1) standards organization. GS1 issues a unique company prefix to each company, which that company uses to generate unique Global Trade Identification Numbers for each product they make.

The use of GTINs to uniquely identify products has superseded the use of 12 digit UPC (universal product code) barcodes, commonly scanned at supermarket checkout stations, which are now treated as a subset of GTINs. The reason for the changeover is that we have run out of available unique UPC codes and so need to use the longer GTINs which can be up to 14 digits long.

But it is important to recognize that the GTIN only represents a unique product code and not a unique container of that product, whose associated data may include lot number, expiration date, and harvesting or processing information. Thus, to uniquely identify a box or other container of a certain product, we need to use a Serialized GTIN (SGTIN) barcode, which is a composite GS1 barcode containing the unique product code plus a serial number assigned by the originator of the tracking barcode on the box, to form a globally unique identification for that specific box of product.

The unique GS1 company prefix is used to generate a unique Global Location Number (GLN) for the main location for the organizations and possibly sub GLNs (SGLNs) for subsidiary locations. These are used to uniquely identify where products are harvested, shipped to, or received from. Each GLN/SGLN location typically has a full associated company/location name and postal address.

The GS1 prefix can also be used to create unique Serial Shipping Container Code barcodes for each shipping container. In our example, these would be used on the pallets of sandwich boxes shipped to the distribution center. They are used to represent and track containers, such as pallets, which may hold many different products, each in their own boxes or other containers.

Thus, our farmer would be expected to:

1. Have a unique prefix assigned by GS1
2. Create product GTINs for the different types of lettuce he sells
3. Print out SGTIN barcodes for each box of lettuce and record the harvesting information for each.
4. Record the GLN or SGLN to which each SGTIN is shipped.
5. Provide harvesting information relative to each SGTIN to the recipient organizations.

And our sandwich maker would be required to

1. Have a unique prefix assigned by GS1
2. Created product GTINs for the different types of sandwich he sells
3. Record the receipt of incoming products from which to make sandwiches by scanning the SGTIN barcodes on each incoming container and recording the relevant information

4. Record the SGTINs from all the boxes or other containers that the materials came to make the batch of sandwiches
5. Print out SGTIN barcodes for each box of sandwiches and record which boxes the batch went into
6. Record the GLN or SGLN to which each box of finished sandwiches SGTIN is shipped or, if they are retail establishments without GLNs, then simply their name and address.
7. Provide information for each customer (downstream supply chain partner) related to:
    a. What materials went into each batch of sandwiches (related to each shipped SGLN)
    b. Originator that made or harvested each input and relevant information
    c. Which distributor or producer, if any, they were received from
    d. Possibly how they were packed (SGLNs on an SSCC coded pallet) for the distribution center.

Technology

Printing out all the unique, situation specific labels, and capturing data by scanning these barcodes is a complex process. For this reason, it is recommended that smaller and mid-sized enterprises use a proven software product such as KnarrTek's BellHawk, which is an integrated barcode data collection and labeling system that performs container-based tracking and automatically captures all the supply chain traceability data needed for FSMA Rule 204 compliance.

A bigger challenge is how to exchange data with a divergent group of supply chain partners. Traditionally, this has been done using ASNs (Advanced Shipment Notices) sent over EDI (Electronic Data Interchange) networks. Today the same information is sent as X12 format messages using secure AS2 protocols over the Internet.

ASN records include the GTIN, lot number, expiration date, and SSCC or SGTIN tracking barcodes for each container of material shipped. They are very useful for reducing the amount of data entry required at time of receipt of material but neither they, nor other X12 format messages, meet the needs of information exchange required by Rule 204, especially when a materials transformation, such as making sandwiches, occurs.

GS1 standard EPCIS (Electronic Product Code Information Services) format files can include all the needed information for data/information exchange and are typically exchanged between larger organizations, over the Internet using a secure protocol such as AS2. These files have a complex format, typically in XML, which need to be generated by computer from data captured electronically at the local site and information received from upstream trading partners.

Thus, these are ideal for our sandwich maker, when receiving traceability data from suppliers such as Sysco or Armata, or sending to traceability partners such as the DC or headquarters for the chain store

Here supply chain integration platforms, such as KnarrTek's MilramX, can generate EPCIS files from event tracking data captured by a system like BellHawk and automate the exchange of EPCIS files with larger supply chain partners. While not inexpensive, these solutions cost a small fraction of the cost of setting up a ghost kitchen and will probably be an integral requirement when setting up such an operation by 2026.

But what about the Gas stations who resell the sandwiches? If they are independent, like many small retailers, they certainly do not have the technological capability to receive EPCIS files or to maintain records about who they sold sandwiches to, except possibly as a result of capturing credit card payments. But if they are part of a major chain, then it will fall to the chain to handle the receipt of traceability data, for sandwiches sold through their gas stations.

For the independent small retailers, probably the best we can to here is to provide a web-portal that a gas station operator could log into and access the traceability data for the boxes of sandwiches that they received; but practically this might not do much good.

Recall of Contaminated Food

The operators of small independent gas stations are unlikely to have more than a passing interest in the origin of the contamination that caused some patrons to collapse in their forecourt after eating their sandwiches or drinking their coffee.

More realistically, it will be something like an outbreak of salmonella poisoning of people eating sandwiches, purchased at local gas stations, that will come to the attention of the CDC (Centers for Disease Control) or IFSAC (Interagency Food Safety Analytics Collaboration) and then the traceback will begin on an interagency basis.

As there is probably little information to be gleaned from the gas stations themselves, tracking back the source of the salmonella, will focus on the records of the sandwich maker, to try to determine the commonality for the outbreak, which would probably lead right back to the farmer who grew the lettuce (as it is on the FTL) or possibly the tomato wholesaler. As, in an ideal world, the sandwich maker will now have all the data and the ability to perform traceback from the contaminated sandwiches to the boxes of lettuce, and therefore the grower, so that the source can be quickly identified.

The ability to track forward, such as from lettuces grown in a specific field to the effected boxes of sandwiches, of the sandwich maker's materials tracking and traceability system can then be used to rapidly recall just the impacted sandwiches before anyone else gets sick. The CDC, or the cognizant state public health authorities, can then issue a more widespread recall for the contaminated batch of lettuce.

But what happens if the sandwich maker did not maintain any records and simply concentrated on making sandwiches. Here, if the sandwiches are determined to be the proximate cause of the outbreak, the FDA will probably shut down the sandwich maker, order the recall of all sandwiches made in the last 3 years, and then proceed with the arduous job of sifting through paper records and physical evidence, such as empty boxes of lettuce, to try to find the source of the contamination. And, as a result, more people will probably get sick or possibly die and the sandwich maker will go out of business.

Commentary

The CDC estimates that each year 1 in 6 Americans get sick from contaminated food or beverages and 3,000 die from foodborne illness. The U.S. Department of Agriculture (USDA) estimates that foodborne illnesses cost the United States more than $15.6 billion each year.

We now have the technology along with the guidance, in FMSA Rule 204, along with standards from GS1, to dramatically speed up finding sources of contamination and in recalling the effected products before more people get sick or die. But complying with Rule 204 will be technically challenging, especially for many small and medium sized family-owned enterprises in the supply chain. This is where organizations such as KnarrTek, who are experts in this area and have the much of the needed technology prebuilt, can provide affordable solutions for these organizations.

Appendix A

The Food Traceability List (FTL) is a list of foods that are subject to additional recordkeeping requirements under FSMA Rule 204. The FTL includes but is not limited to:

- Many fresh fruits and vegetables, including all leafy greens, melons, sprouts, cucumbers, tomatoes, peppers, herbs, tropical tree fruits, and all fresh-cut items.
- Cheeses, other than hard cheeses
- Shell eggs
- Nut butter
- Some categories of seafood
- Ready-to-eat deli salads (refrigerated)

Critical Tracking Events (CTEs) include:

- Harvesting
- Cooling
- Initial Packing
- First Land-Based Receiver
- Shipping
- Receiving
- Transformation

Under the FSMA Rule 204, Key Data Elements (KDEs) are required for each Critical Tracking Event (CTE) in the food’s supply chain.

Here is an example of KDEs for a lettuce growing farm

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as field or growing area name

A full list of KDEs for different CTEs is available from the FDA.gov website.

Authors

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Dr. Peter Green serves as the Technical Director of KnarrTek Inc. Dr Green obtained his BSC (Hons) in Electrical Engineering and his Ph.D. Degrees in Electronics and Computer Science from Leeds University in England. Subsequently Dr. Green was a senior member of technical staff at Massachusetts Institute of Technology and a Professor of Computer Engineering at Worcester Polytechnic Institute.

Dr Green is a systems architect who is an expert in technology solutions for materials tracking and traceability in the food, medical, industrial, construction and defense supply chains. He has led the implementation of over 100 such systems over the past decade. Dr Green also led the team which developed the BellHawk barcode tracking, labeling, materials tracking and traceability software as well as the MilramX decision support and supply chain information integration software platform.

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Eric Green serves as the Director of Support of KnarrTek Inc. Eric Green obtained is bachelor's degree from UMASS Dartmouth in Operations Management and Management Information Systems. Eric has been a part of 40 plus implementations of operations management systems over his 8 years of experience in this field. This includes receiving, production, inventory management, shipping, order management, as well as integrations with a number of ERP systems and a range of different manufacturing equipment.

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