GCCA'S FSMA 204 "DEEP DIVE"

Acronyms

- *FSMA 204: Additional Traceability Records for Certain Foods/Food Traceability Final Rule*
- *FTL: Food Traceability List*
- *KDE: Key Data Elements*
- *CTE: Critical Data Events*
- *3PL: Third-party logistics*
- *FSMA: Food Safety Modernization Act*
- *TLC: Traceability Lot Codes*
- *ASN: Advance Shipment Notice*
- *PFT: Partnership for Food Traceability*

FSMA 204 Summary

On November 15, 2022, the FDA published the final rule on Requirements for Additional Traceability Records for Certain Foods (also called Food Traceability Final Rule or FSMA 204). The rule establishes traceability recordkeeping requirements for those who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). At its core, the rule requires businesses to maintain records containing Key Data Elements (KDEs) for specific supply chain activities known as Critical Tracking Events (CTEs), which include harvesting, cooling, initial packing, receiving, shipping, and transformation.

The information must be provided to FDA within 24 hours or some reasonably agreed upon time in a sortable spreadsheet. The FDA provides a template for this spreadsheet. Columns can be added but none should be removed.

To be compliant with FSMA 204, facilities must have a Traceability Plan. This plan must include: a description of procedures used to maintain required records (format and location); procedures used to identify FTL foods; how traceability lot codes (TLCs) are assigned; a point of contact for questions; and, for farms, a farm map showing all growing

areas with geographic coordinates. The traceability plan must be updated as practices change, and prior versions must be retained for two years after updates. A template is in annex to this document.

For third-party logistics (3PL) and cold storage operators, the rule carries particular significance because they will be expected to maintain systems that support all customer compliance obligations. Process standardization is essential to reduce costs and minimize the risk of non-compliance.

Background

FSMA 204 was born from a pattern of deadly outbreaks and is a key component of FDA's Food Safety Modernization Act (FSMA). Congress enacted FSMA in response to changes in the global food system and in the understanding of foodborne illness and its consequences. FSMA aimed to shift the focus of federal regulators from responding to contamination to preventing it. It provided FDA, for the first time, with a legislative mandate to require comprehensive, prevention-based controls across the food supply.

Even with FSMA's broader prevention framework in place, outbreak investigations remained slow and difficult because supply chain records were fragmented or incomplete. In Section 204, Congress directed FDA to improve the tracking and tracing of food through the supply chain by establishing additional recordkeeping requirements for facilities handling certain foods frequently associated with foodborne illness outbreaks with the intent of enabling more efficient removal of products from the market in the case of an outbreak leading to a recall. The goal was to shorten the time it takes for a product to be traced from retailers and distributors back to where it originated.

The new requirements identified in the final rule are intended to allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

Traceability Lot Codes, Sources, and Source References

The traceability lot code (TLC) links to the other KDEs required, including the TLC Source, which provides the physical location where the TLC for an FTL food was assigned. Unless the relevant entity is exempt from FSMA 204, the traceability lot code is assigned when the food is initially packed, received by the first land-based receiver, or transformed. Once a TLC is assigned, it must stay the same as the food moves through the supply chain; it can only be changed if the food is transformed.

A TLC is used to uniquely identify a traceability lot within the records of the traceability lot code source (TLC source), which refers to the physical location where a food was assigned

a traceability lot code. For some CTEs, the Food Traceability Rule requires documentation of either the location description for the TLC source, or the TLC source reference.

Location description means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country. Importantly, it is the key contact information for the place where the food was assigned a traceability lot code.

A traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source. If a firm chooses to use a traceability lot code source reference, they can set it up in a way that will maintain the confidentiality of business information concerning suppliers.

Shipping CTE

This CTE applies any time an FTL food is shipped. The shipper must both maintain and provide most of these KDEs to the next recipient in the supply chain. It does not apply to shipments of raw agricultural commodities before initial packing.

The following KDEs must be maintained and shared on the following:

- Traceability lot code (TLC)
- Quantity and unit of measure
- Product description
- Location description for the immediate subsequent recipient (not the transporter)
- Location description for the location from which the food was shipped
- Date shipped
- Location description for the TLC source or the TLC source reference
- Reference document type and reference document number (maintained only, not shared)

TLC Source is the physical location where a food product's TLC was assigned. The TLC Source Reference is the alternative identifier that provides the FDA with access to the physical location where a food product's TLC was assigned, without exposing sensitive supplier information to other supply chain partners

Receiving CTE

This CTE applies when an FTL food is received by any covered entity. It mirrors many of the Shipping KDEs but from the receiver's perspective. It does not apply to receipt before initial packing or to first land-based receivers of fishing vessel food.

The following KDEs must be received:

- TLC for the food
- Quantity and unit of measure
- Product description
- Location description for the immediate previous source (not the transporter)
- Location description for where the food was received
- Date received
- Location description for the TLC source or TLC source reference
- Reference document type and reference document number

There are some modifications if the supplier is exempt. In this case, the following KDEs must be received:

- TLC must be assigned by the receiver if one has not been assigned
- Quantity and unit of measure
- Product description
- Location description for the immediate previous source
- TLC Source or TLC Source reference.
- Date received
- Reference document type and reference document number

Transformation CTE

This CTE applies when an FTL food is transformed into a new product and includes manufacturing, processing, commingling, repacking, or relabeling. When transformation occurs, a new TLC must be assigned, and KDEs must be recorded for both the ingredient(s) used and the new food produced.

For ingredients, the following KDEs must be recorded:

- TLC for each ingredient food
- Product description for the food to which each TLC applies

- Quantity and unit of measure of the food used from each lot

For new food produced, the following KDEs apply:

- New TLC for the food
- Location description for where transformation occurred (i.e., TLC source) or TLC source reference
- Date transformation was completed
- Product description
- Quantity and unit of measure
- Reference document type and reference document number

Applicability

The Food Traceability Rule applies to organizations that manufacture, process, pack, or **hold foods**. **Even though 3PLs do not take ownership, they fall under the regulation as it is written and are recommended to prepare for compliance**. There are ongoing discussions regarding the extent to which 3PLs can ensure the validity of data which is provided by customers and GCCA is working with coalition partners to explore flexibilities in this area.

Exceptions and Exemptions

Most exemptions are based on product, farm size or relate to fishing capture area, but for a full list of exemptions, please visit the FDA website or the Code of Federal Regulations. The following are exceptions and exemptions that may apply to GCCA members.

- Transporters of food are exempt unless they take ownership of the product.
- Entities not handling Food Traceability List (FTL) items are exempt from the rule entirely.
- The rule applies to all food facilities except meat, poultry, and certain egg producers, which are regulated by the U.S. Department of Agriculture.
- If produce is on the Rarely Consumed Raw List, it is exempt.

Partial Exemptions may also apply in some circumstances:

- If a product is commercially processed in a way that eliminates pathogens (kill-step processing such as pasteurization or canning), it may be exempt, as long as proper documentation of that process is in place. Please note that freezing is not considered a kill-step.

- Grocery stores and restaurants with 10 or fewer full-time employees may be eligible for exemption from some of the requirements.
- "Very Small Business", which are defined as averaging less than $1,000,000 in annual sales (adjusted for inflation) of human foods may qualify for modified requirements.
- Retail food establishments and restaurants with annual food sales under $250,000 receive a full exemption, while those under $1,000,000 in annual sales qualify for a partial exemption with limited records required

It should be noted that even if a regulatory exemption applies, customers may still require compliance. Many upstream supply chain partners are moving toward full traceability, even for non-FTL items. Also, many exemptions, particularly those based on business size or production volume, are subject to change as a company grows.

Flexibilities

FSMA 204 provides several key flexibilities to help businesses comply with FDA food traceability requirements. Core flexibilities include:

- **Record Formats:** The FDA does not mandate a specific technology or software. Traceability records may be paper records, electronic records, or true copies.
- **Traceability Lot Code (TLC) Transmission:** The TLC is not required to be printed directly on the product's packaging. It can be shared digitally, via an Advance Shipment Notice (ASN), on a bill of lading, or embedded in a QR code.
- **Supply Chain Documentation:** A new, unique document is not required; records already kept in the normal course of business are acceptable.
- **Interconnected Traceability Systems:** If FTL foods are transformed, consolidated, or repackaged, businesses have the flexibility to design their own systems linking the new Traceability Lot Code back to the original TLC of the ingredients received.
- **Lot-Level Tracking Flexibilities (In Progress):** Congress has directed FDA to engage quarterly with regulated entities to identify and implement additional flexibilities for satisfying the rule's lot-level tracking requirement, consistent with the statutory prohibition on requiring product tracking to the case level. FDA is also required to provide industry stakeholders with recommendations for these additional flexibilities within 180 days of enactment, and to provide assistance on how to handle food waste recovery, reclamation, intra-company transfers, and customer returns under the rule. GCCA is monitoring and providing input on this process through the Partnership for Food Traceability.

Under discussion now with FDA and the Partners for Traceability coalition (see details under Coordination Activities) are the flexibilities that can be sought to facilitate ease of compliance. One potential flexibility under current discussion includes Distributors as Transformers, which would enable distributors to assign a new TLC and TLC Source Reference and pass that data downstream. Should this be allowed by FDA, it is proposed as one option for those whom it would benefit; other flexibilities should also be available to meet other needs/situations/use cases.

Traceability Plans

There is no specific format required for the traceability plan, but the information in the traceability plan must reflect the current practices specific to the covered entity and must contain the following requirements (as described in § 1.1315 of the Food Traceability Rule).

1. A description of the procedures used to maintain the records an entity is required to keep, including the format and location of these records.
2. A description of the procedures used to identify foods on the Food Traceability List that the entity manufactures, processes, packs, or holds
3. A description of how TLCs are assigned to foods on the Food Traceability List, if applicable;
4. A statement identifying a point of contact for questions regarding the traceability plan and records.
5. Farms must include a farm showing the areas in which FTL foods are grown or raised.
6. The traceability plan must be updated as needed to ensure that the information provided reflects current practices and to ensure that an entity is in compliance with the requirements of the Food Traceability Rule. Previous traceability plans must be kept for 2 years after the plan is updated.

GCCA has drafted a customizable FTL plan in Annex, specifically for 3PLs. FDA also has a more general template.

Coordination Activities

There are two active coalitions in which GCCA participates. GCCA is a member of the Partnership for Food Traceability, which is a public-private partnership between the broader food industry and FDA. GCCA sits on the Traceability Committee and the Pilots committee. Each Committee meets biweekly. The Partnership for Food Traceability (PFT) is an independent, sector-neutral nonprofit developing a shared, overarching vision for food traceability across the supply chain. PFT's membership includes industry members, trade

associations, and technology vendors from all sectors and industries of the food supply chain with support from FDA, State, and local food officials.

GCCA also joined the Food Industry FSMA 204 Collaboration, organized by GS1. The goal of the Collaboration is to share clear messaging and resources to help industry take action in preparing for FSMA Rule 204 and brings together key trade associations and industry groups to provide resources supporting education and guidance for FSMA Rule 204 and support the necessity of widespread compliance

Timelines

The original compliance date for all persons subject to the recordkeeping requirements of the Food Traceability Rule was Tuesday, January 20, 2026, but the FDA extended the compliance date for the rule by 30 months to July 20, 2028.

Next Steps

Regulated facilities have until **July 20, 2028**, to comply with the requirements of the Food Traceability Rule.

During this time, the FDA is collaborating with industry organizations to determine flexibilities to facilitate compliance in areas determined to be more complicated such as eaches, intracompany transfers, and traceability lot code and traceability lot source code assignments. The FDA does not plan to provide guidance or recommendations on methods for compliance.

GCCA will continue to provide members updated information regarding FSMA 204 requirements through the July 2028 deadline.

- Members should familiarize themselves with the rule provisions and consider the steps necessary to comply.
- Interested and involved members are also strongly encouraged to join the **FSMA 204 Working Group.**
- Frequently Asked Questions: FSMA Food Traceability Rule | FDA
- Additional FSMA 204 Resources from GCCA can be accessed at www.gcca.org

For additional information or questions, please contact the Global Cold Chain Alliance at advocacy@gcca.org.