How to Comply with New FSMA Section 204 Recordkeeping Requirements

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Meet Your Moderator

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TRACEGAINS

Meet Your Speakers
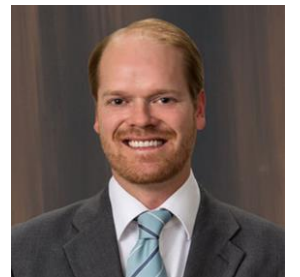
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TRACEGAINS

Who is subject to the proposed rule?

Unless otherwise specified, persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required

- Full or partial exemptions
- Waivers

Food Traceability List (FTL)

- Cheeses, other than hard cheeses
- Shell eggs
- Nut butter
- Cucumbers (fresh)
- Herbs (fresh)
- Leafy Greens (fresh)
- Melons (fresh)
- Peppers (fresh)

- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh-cut)
- Fruits and Vegetables (fresh-cut)
- Finfish, including smoked finfish
- Crustaceans
- Mollusks, bivalves
- Ready-to-eat deli salads

What is exempt from the proposed rule?

- **Small originators**
  - **Certain small/local produce farms (less than $25K in annual sales or eligible for a qualified exemption)**
  - **Certain shell egg producers (less than 3,000 laying hens)**
  - **Other small originators (less than $25K in annual sales)**
- **Transporters of food**
- **Nonprofit establishments**
- **Food for personal consumption**

What is exempt from the proposed rule?

- **Farms**
  - **When food is produced on the farm and sold DIRECTLY to a consumer**
  - **When food is packaged on the farm, and:**
    - **The packaging remains in place until the food reaches the consumer;**
    - **The packaging maintains the integrity of the food and prevents subsequent contamination or alteration of the food; and**
    - **The packaging includes the name, complete address, and business phone number of the farm**

What is exempt from the proposed rule?

- **Foods that receive certain types of processing**
  - Produce that receives commercial processing that adequately reduces presence of microorganisms of public health significance per 21 CFR 112.2(b)
  - Shell eggs that receive treatment per 21 CFR 118.3
- **Produce that is rarely consumed raw [listed in 21 CFR 112.2(a)(1)]**
- **Persons that hold food on behalf of individual consumers**
  - Are not parties to the transaction involving the food they hold, and
  - Are not in the business of distributing food

What is exempt from the proposed rule?

- **Partial exemption for commingled raw agricultural commodities that are not covered by the Produce Safety Rule**
  - When the commodity is combined or mixed with food from different farms; and
  - Such combining/mixing happens after harvesting, but before processing

- **Partial exemption for fishing vessels**

- **Why are these partial? If you are required to register with the FDA, you must:**
  - Maintain records identifying the immediate previous source and immediate subsequent recipient of the food
  - Keep records for 2 years

What is exempt from the proposed rule?

- **Partial exemption for retail establishment that purchases food produced on a farm directly from the farm**

- **Partial exemption for farm-to-school or farm-to-institution program that purchases food produced on a farm**

- **Why are these partial?**
  - **Must establish and maintain records that document the name and address of the farm that supplied the food**
  - **Keep records for 180 days**

What is exempt from the proposed rule?

- **Small retail food establishments (10 or less full-time equivalent employees)**

- **Option 1**
  - **Full exemption from rule**

- **Option 2**
  - **Only exempt from requirement to provide FDA with an electronic sortable spreadsheet upon request**

Critical Tracking Event (CTE)

An event in the supply chain of a food involving the growing, receiving (including first receipt by a first receiver), transforming, creating or shipping of food

Key Data Element (KDE)

Information associated with a critical tracking event for which a record must be established and maintained in accordance with this subpart

Reference Record

A record used to identify an event in the supply chain of a food, such as a shipping, receiving, growing, creating, or transformation event.

- Bills of lading
- Purchase orders
- Advance shipping notices
- Work orders
- Invoices
- Batch logs
- Production logs
- Receipts

Key Terms

- **Traceability Lot Code**
  - A descriptor, often alphanumeric, used to identify a traceability lot
- **Traceability Product Description**
  - A description of a food product typically used commercially for purchasing, stocking, or selling, and includes the category code or term, category name, and trade description
    - **Single ingredient products** – Trade description includes the brand name, commodity, variety, packaging size, and packaging style
    - **Multiple ingredient products** – Trade description includes the brand name, product name, packaging size, and packaging style

When to establish and assign traceability lot codes for food on the FTL

- Originate – CTE that involves the growing, raising, or catching of a food, or harvesting a non-produce commodity

- Transform – CTE that involves changing a food on the FTL, its package, and/or its label

- Create – CTE that involves making or producing a food on the FTL from ingredients not on the FTL

Grow/Originate

- Establish and maintain records containing and linking the traceability lot code to:
  - Growing area coordinates
- Fishing Vessels
  - Harvest date range and locations (National Marine Fisheries Service Ocean Geographic Code or GPS coordinates)

First Receiver

- Establish and maintain records containing and linking the traceability lot code to:
    - The location identifier and location description of the originator of the food
    - The business name, point of contact, and phone number of the harvester of the food , and the date(s) and time(s) of harvesting
    - The location identifier and location description of the place where the food was cooled, and the date and time of cooling
    - The location identifier and location description of the place where the food was packed, and the date and time of packing
- May need to establish a traceability lot code when an originator has not assigned a traceability lot code

Receive

- Establish and maintain records containing and linking the traceability lot code to:
    - The location identifier and location description for the immediate previous source
    - Entry number assigned to food (if imported)
    - The location identifier and location description of where the food was received, and the date and time the food was received
    - The quantity and unit of measure of the food
    - The traceability product identifier and traceability product description for the food
    - The location identifier, location description, and point of contact for the traceability lot code generator
    - The reference record types and numbers for documents containing the information
    - The name of the transporter who transported you the food

Transform

- For foods used in transformation
  - Traceability lot codes for the food
  - Traceability product identifier and traceability product description
  - The quantity of each traceability lot of food
- For food produced through transformation
  - Location identifier and location description of where you transformed the food, and the date the transformation was completed
  - The new traceability product identifier and traceability product description for food to which the new traceability lot code applies
  - The quantity and unit of measure of the food for each new traceability lot code
  - The reference record types and reference record numbers for documents containing the information

Create

- Establish and maintain records containing and linking the traceability lot code to:
    - Location identifier and location description of where you created the food, and the date the creation was completed
    - Traceability product identifier and traceability product description
    - The quantity and unit of measure of the food
    - The reference record types and reference record numbers for documents containing the information

Ship

- Establish and maintain records containing and linking the traceability lot code to:
    - Entry number assigned (if imported)
    - Quantity and unit of measure of the food
    - Traceability product identifier and traceability product description of the food
    - Location identifier, location description, and point of contact for the traceability lot code generator
    - Location identifier and location description for the immediate subsequent recipient (other than a transporter) of the food
    - Location identifier and location description for the location from which you shipped the food, and the date and time you shipped the food
    - Reference record types and numbers containing the information
    - The name of the transporter who transported the food from you

Kill Step?

- If you apply a kill step, the requirements do not apply to your subsequent shipping of the food
    - Need to keep records of you kill step
- 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

Program development

- A description of reference records in which you maintain required information

- An explanation of where on the records the required information appears, and a description of how reference records are linked

- A list of food on the Food Traceability List that you ship, including the traceability product identifier and traceability product description

- A description of how you establish and assign traceability lot codes to foods on the Food Traceability List

- Any other information needed to understand the data provided in any records (e.g.coding systems, glossaries, abbreviations

Record Maintenance and Availability

- Must provide records as soon as possible, but not later than 24 hours after request
- If necessary to hep the FDA prevent or mitigate a foodborne illness outbreak, assist in implementation of a recall, or otherwise address a threat to public health
  - Must make available an electronic sortable spreadsheet containing the information in the records required under the rule

Compliance Schedule

- Final rule – November 2022
- Compliance
  - Two years after publication of final rule

Questions?

TraceGains Network

**Freedom from tracking
down suppliers and requesting
information or documents**

46K+
Supplier Locations

530K+
Items & Ingredients

3M+
Supplier, Item & Ingredient Documents

150+
Standardized Online Forms

130+
Supplier Countries

Our Solution

A Standard, Centralized and Digitized Approach to Controlling the Verification of Materials and Ingredients

Industry Standards

for Data Collaboration

Industry Standard Data

Digitization and Automation

New Product Development Suite

Supplier Management

The definitive industry solution for ingredient supplier documentation and data.

THE PROBLEM
You need vast amounts of supplier documentation to run your business.
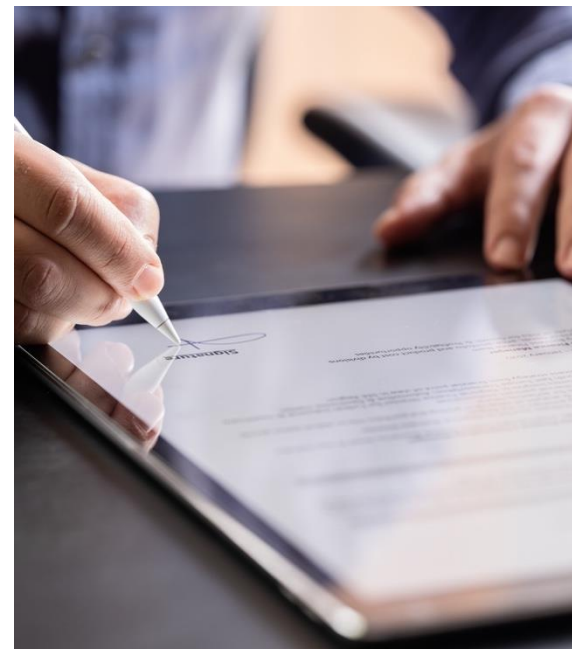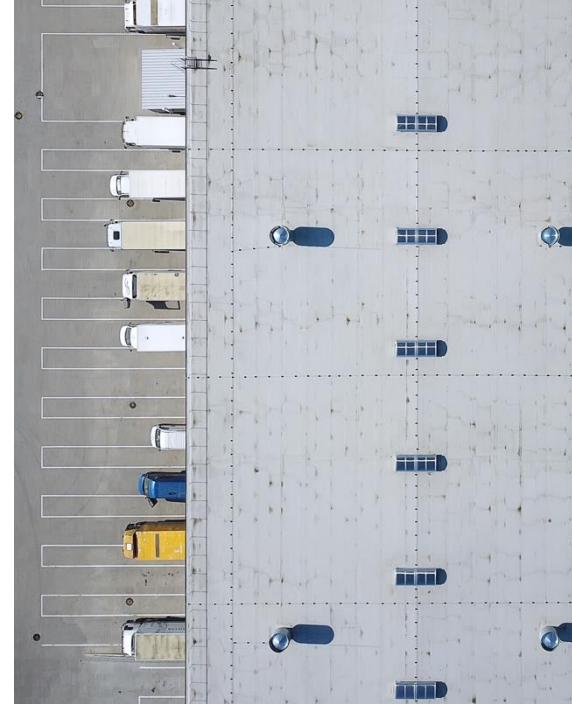
WHY IT MATTERS
Cumbersome and repetitive document management slow down sourcing.

THE SOLUTION
Digital documents and data enable re-use, insights and automation.

THE TRACEGAINS DIFFERENCE
Powered by almost 20,000 suppliers in the TraceGains supplier ecosystem.

Specification Management

Collaboratively author, publish, and update
raw material and finished goods specifications.

THE PROBLEM
Manual and error-prone processes slow down
collaboration and add risk.

WHY IT MATTERS
Quality, Production, and Time-to-Market all
depend on solid specification processes.

THE SOLUTION
Bring all parties together in a collaborative
digital environment.

THE TRACEGAINS DIFFERENCE
Real-time digital collaboration powered by
TraceGains Network.

Smart Alerts

Real-time fraud and regulatory risk monitoring for your supply chain.

THE PROBLEM
Critical risk data that lives externally may not be there when you need it.

WHY IT MATTERS
Fraud, allergens, contamination, foreign material, recalls and bad actors.

THE SOLUTION
Configurable alerts from the industry's most authoritative sources, always up to date.

THE TRACEGAINS DIFFERENCE
Customized alerts driven by the needs of your business, and there when it matters most.

Supplier Compliance

Accelerated sourcing with supplier scorecards and industry intelligence.

THE PROBLEM
Risk and variability can be hard to spot, and outstanding supplier performance easy to miss.
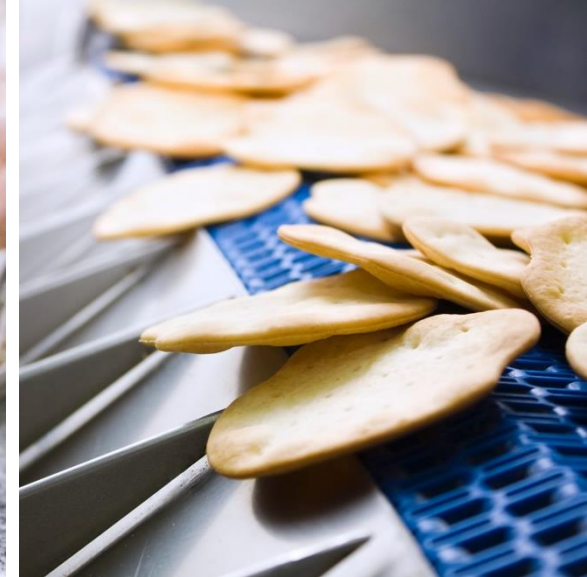
WHY IT MATTERS
A single issue can drive huge costs, while tiny trends can hurt over time.

THE SOLUTION
Score performance, customize templates and automate processes.

THE TRACEGAINS DIFFERENCE
Real-time information integrated with ingredient specification-level data.

Value Across the Organization

TraceGains brings people and information together.

- **Single Source of Truth to Identify Items** that are affected by global regulations, such as FSMA §204.

- **Standardized Forms** adapt to KDE requirements via **collaboration** with TAG and TG's Customer Advisory Board.

- **Capture Lot-based Attributes** of materials impacted by regulatory rules. Visibility and control to meet product quality and regulatory compliance requirements.

- **R&D / Procurement** can identify FTL items and its impact on usage in formulations and product marketing.

TraceGains Export Tools and API's

- ✓ Pass Data Back And Forth From ERP Or PLM Systems To TraceGains
- ✓ Connect all systems of record.

Delivers complete supply chain transparency with a single pane of glass

Live Q&A

Thank You

Plug In. Go Faster.