

Proposed Rule: Requirements for Additional Traceability Records for Certain Foods

(FSMA Section 204)

Aleta Flores, CFSAN Office of Compliance
Presentation to the Washington Association for Food Protection
September 16, 2021



U.S. FOOD & DRUG
ADMINISTRATION

Background

- ***Proposed Rule:*** Published on September 23, 2020
- ***Public Comment period:*** Ended February 22, 2021
- ***Final Rule:*** Under consent decree, FDA must submit a final rule to the Office of the Federal Register by November 2022
- ***Compliance date*** for all covered entities to be 2 years from the effective date of the final regulation.

Why is traceability important?

- When a foodborne illness outbreak occurs, we need to quickly identify and remove the contaminated food from the market to avoid additional illnesses/deaths
- Need accurate information on the food to trace it back through the supply chain to identify the source and also forward to determine how the food was distributed

Current State

Exit Payment To

Page 1 of 2

Distributor A
Nashville TN

LOCAL : 615-255-2900 8111 TN
TOLL :
FAX : 615-255-2900

SHIP To: Distributor A
NASHVILLE TN 37210
ADDRESS: 2700

| Invoice No. | Invoice Date | Customer No. | Order Date | P.O. Number | Salesman | Terms | Route-Stop |
|-------------|--------------|--------------|------------|----------------|------------|-------------|------------|
| 245037 | 4/24/19 | 729 | 4/24/19 | 1150872/L22140 | UNASSIGNED | NET 30 DAYS | WVC |

SPECIAL INSTRUCTIONS: 1150872 FRIDAY 04/26/2019 08AM045

| Item Number | Quantity Ordered | Quantity Shipped | Pack | Size | Item Description | Unit Weight | Extended Weight | Unit Price | Extended | ST |
|-------------|------------------|------------------|------|------|------------------------------------|-------------|-----------------|------------|----------|----|
| 865802 | 170 | 170 | 250 | 250 | TOMATOES UTILITY 250 | -7302204 | | | | |
| 867133 | 100 | 100 | 100 | 100 | 250 CAFE | -3796291 | | | | |
| 867180 | 60 | 60 | 120 | 120 | TOMATO GRAPE 12/1 Pint | -6959383 | | | | |
| 861291 | 60 | 60 | 250 | 250 | TOMATOES S&S 250 | -4851412 | | | | |
| 862311 | 100 | 100 | 250 | 250 | 250 ROMA CPE-ROT A UTILITY-3449095 | | | | | |
| 866608 | 10 | 10 | 250 | 250 | ROMA CPE-ROT A UTILITY-3449095 | | | | | |
| 861450 | 8 | 8 | 250 | 250 | TOMATOES ROMAS 250 Fresh-2095730 | | | | | |
| 861707 | 40 | 40 | 200 | 200 | 4x4 2-Layer DEEP RED VS | -3064907 | | | | |
| 861452 | 100 | 100 | 200 | 200 | TOMATO DEEP RED VINE RIPE | -8131084 | | | | |
| 861452 | 100 | 100 | 200 | 200 | TOMATOES S&S 2-Layer | -1079219 | | | | |
| 861452 | 100 | 100 | 250 | 250 | 250 S&S | -132782 | | | | |

MARKET: NASHVILLE, TN

Driver: [REDACTED] Cash Amount: [REDACTED] Check Amount: [REDACTED] Check my merchandise before signing Customer Signature: [REDACTED] Total Weight: [REDACTED] Sub Total: [REDACTED]

Receiving for Distr. A

Tomato

Door 3

28

NASHVILLE, TN 37210
PHONE: 615 [REDACTED] 735

TERMS: N/ LEAD: DAYS FRT: [REDACTED]

BROKER: BUYER: AM

R.R. CAR#: [REDACTED]
R.R. SEAL#: [REDACTED]

SHIP DATE: 4/25/2019
DELIVERY DATE: 4/26/2019

| UPC NUMBER | ITEM DESCRIPTION | CL | ITEM | SLOT LOC | ORDER | REC'D | AVG WGT | WGT REC |
|------------|--------------------------|----|-----------------|----------|-------|-------|---------|---------|
| 9500 | TOMATO CAFE CT USU | 0 | 22553 C 01C075A | 170 | 170 | ✓ | 4590.00 | |
| Quality: | TOMATO GRAPE 16LB | 0 | 22542 C 01C064A | 180 | 180 | ✓ | 1980.00 | |
| Quality: | TOMATO GRAPE 12PT | 0 | 22533 C 01C073A | 60 | 60 | ✓ | 660.00 | |
| Quality: | TOMATO LARGE ROUNDS 25LB | 0 | 22531 C 01C069A | 60 | 60 | ✓ | 1560.00 | |
| Quality: | TOMATO ROMA 25LB | 0 | 22490 C 01C072A | 180 | 180 | ✓ | 4860.00 | |
| Quality: | TOMATO SELECT 25LB USU | 0 | 22556 C 01C079A | 10 | 10 | ✓ | 270.00 | |
| Quality: | TOMATO 4X4 | 0 | 22500 C 01C078A | 8 | 8 | ✓ | 176.00 | |
| Quality: | TOMATO 4X5 CCF | 0 | 22507 C 01C077A | 40 | 40 | ✓ | 880.00 | |
| Quality: | TOMATO 5X5 20LB LAYER | 0 | 22511 C 01C076A | 104 | 104 | ✓ | 1976.00 | |
| Quality: | TOMATO 5X5 20LB LAYER | 0 | 22501 C 01C074A | 80 | 80 | ✓ | 2160.00 | |

Distributor A
Nashville TN

28

RECEIVING PURCHASE ORDER

TERMS: N/ LEAD: DAYS FRT: [REDACTED]

SHIP / DELIVERY DATE: 4/25/2019

| UPC NUMBER | ITEM DESCRIPTION | CL | ITEM | SLOT LOC | ORDER | REC'D | AVG WGT | WGT REC |
|------------|--------------------------|----|-----------------|----------|-------|-------|---------|---------|
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| Quality: | TOMATO LARGE ROUNDS 25LB | 0 | 22531 C 01C069A | 60 | 60 | ✓ | 1560.00 | |
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| Quality: | TOMATO 5X5 20LB LAYER | 0 | 22511 C 01C076A | 104 | 104 | ✓ | 1976.00 | |
| Quality: | TOMATO 5X5 20LB LAYER | 0 | 22501 C 01C074A | 80 | 80 | ✓ | 2160.00 | |

Distributor D
Nashville TN

28

RECEIVING PURCHASE ORDER

TERMS: N/ LEAD: DAYS FRT: [REDACTED]

SHIP / DELIVERY DATE: 4/25/2019

| UPC NUMBER | ITEM DESCRIPTION | CL | ITEM | SLOT LOC | ORDER | REC'D | AVG WGT | WGT REC |
|------------|--------------------------|----|-----------------|----------|-------|-------|---------|---------|
| 9500 | TOMATO CAFE CT USU | 0 | 22553 C 01C075A | 170 | 170 | ✓ | 4590.00 | |
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Benefits of the Food Traceability Proposed Rule

- Potential to reduce foodborne illnesses/deaths
 - Faster identification of source of contamination
 - Rapid removal of contaminated food from market
- Potential to limit the scope of recalls
- Harmonized information
 - Establish linkages along supply chain more quickly
- Aligns with current industry approaches
- Would enhance ability to conduct root cause investigations to identify and apply lessons learned from outbreaks
- Greater transparency + supply chain intelligence

Advancing Traceability

- Food Traceability proposed rule is a first step
- Will help to harmonize Key Data Elements and Critical Tracking Events across industry
- New Era for Smarter Food Safety will build on this foundational work
- Ultimate goal is end-to-end traceability throughout the food system

Key Concepts of the Proposed Rule



Touches the whole supply chain from farms and facilities to retail food establishments



Includes both foreign and domestic entities



Only applies to certain foods



Some exemptions and partial exemptions

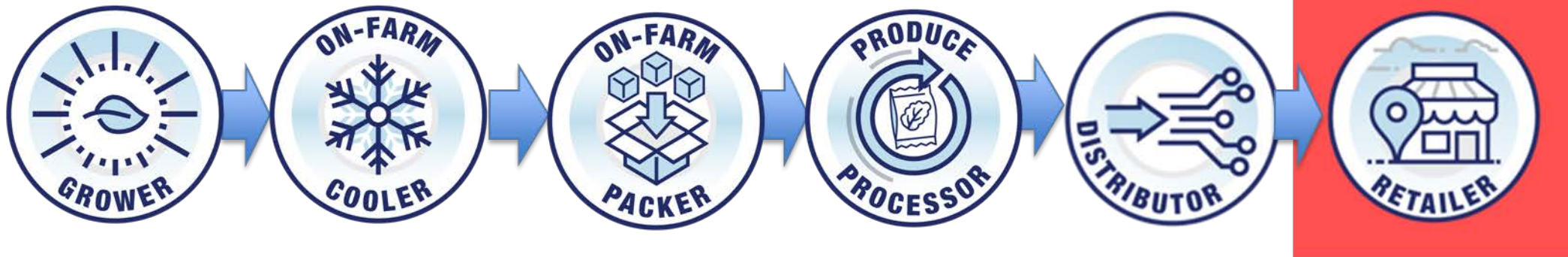


Co-proposal on Retail Food Establishments

WHO IS COVERED?

- Persons who manufacture, process, pack, or hold foods on the **Food Traceability List**

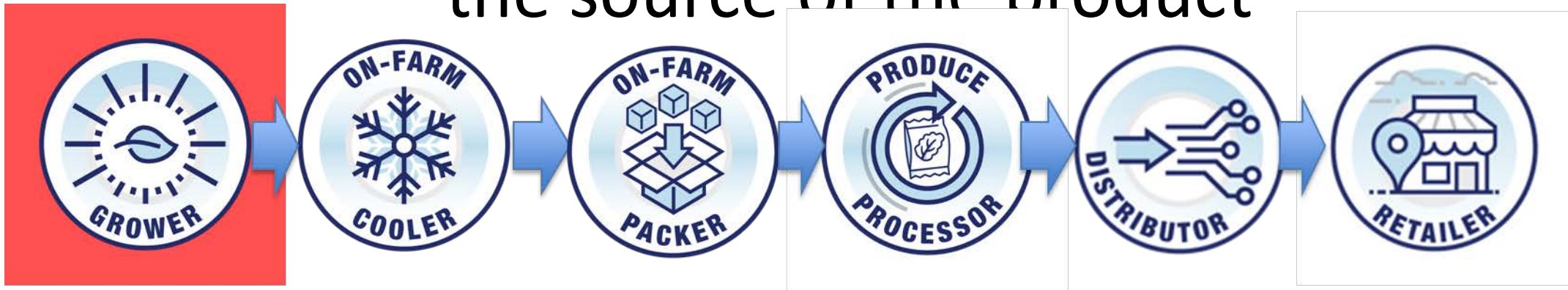
Instead of going to
each point in the chain...



- **At each point in the chain:**

- Asking questions on the product received
- Gathering non-standardized information in paper and/or electronic format
- Different terminology and lack of connectivity
- Asking the firm clarifying questions

Reducing the time it takes to identify the source of the product



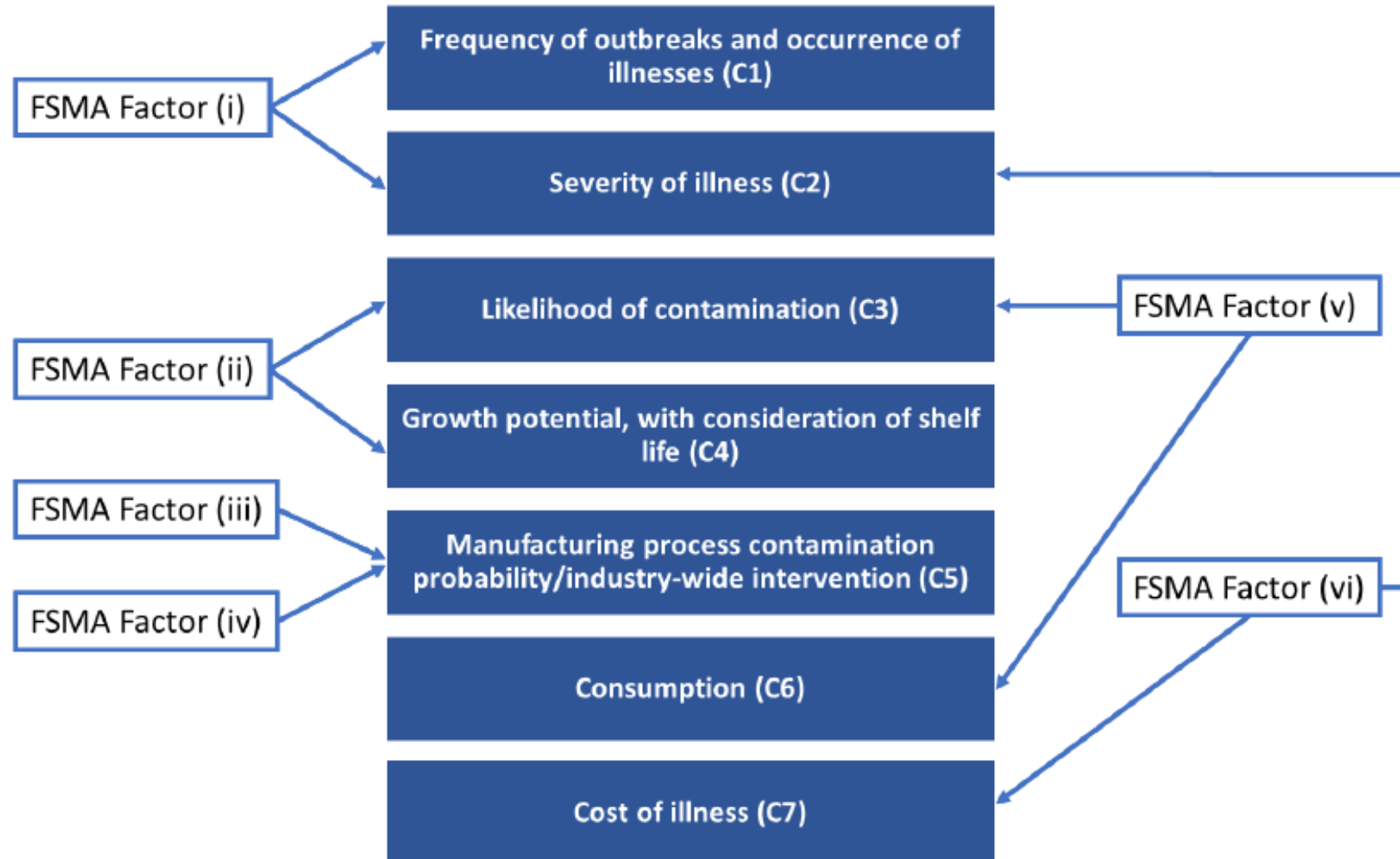
- **Vision:**

- Asking for **KDEs related to an entity's CTEs** for a certain time period
- Gathering **standardized** information in paper and/or electronic format
- **Traceability lot code** and **traceability lot code generator** helps us “skip” back to the source faster
- Reducing clarifying questions by having the **Traceability Program Records**

Foods for which Additional Traceability Records would be Required

- To determine which foods should be included on the **Food Traceability List (FTL)**, FDA developed a Risk-Ranking Model for Food Tracing
- The model scores commodity-hazard pairs according to data and information relevant to the criteria identified in FSMA
- Under the proposed rule, foods designated as high-risk are listed on the FTL
- These are the foods for which traceability records will be required

Alignment of Model Criteria and Statutory Factors Required by FSMA



Food Traceability List

| Food Traceability List | Food Traceability List |
|--|-----------------------------------|
| Cheeses, other than hard cheeses | Sprouts (fresh) |
| Shell eggs | Tomatoes (fresh) |
| Nut butter | Tropical tree fruits (fresh) |
| Cucumbers (fresh) | Fruits and Vegetables (fresh-cut) |
| Herbs (fresh) | Finfish, including smoked finfish |
| Leafy greens (fresh), including fresh-cut leafy greens | Crustaceans |
| Melons (fresh) | Mollusks, bivalves |
| Peppers (fresh) | Ready-to-eat deli salads |

Overview of Exemptions

| Statutory Exemptions | Statutory Partial Exemptions |
|--|---|
| Farms selling food directly to consumers | Certain commingled RACs (not fruits & vegetables) |
| Food produced/packaged/labeled on farm | Fishing vessels |
| | Farm-to-school/institution programs |
| Additional Proposed Exemptions | Additional Proposed Partial Exemptions |
| Very small farms | Retail food establishments receiving food directly from a farm (expanded from “grocery stores”) |
| Produce and shell eggs that receive certain processing | |
| Produce on FDA’s “rarely consumed raw” list | |
| Transporters of food | |
| Non-profits, personal consumption | |

*In addition, traceability records would not be required after a **kill step** is applied. A record of the kill step application would have to be maintained by the person who applied the kill step.

Proposed Requirements

Critical Tracking Events

Growing, receiving, transforming, creating, and shipping are Critical Tracking Events (CTEs) for which records would be required.

Key Data Elements

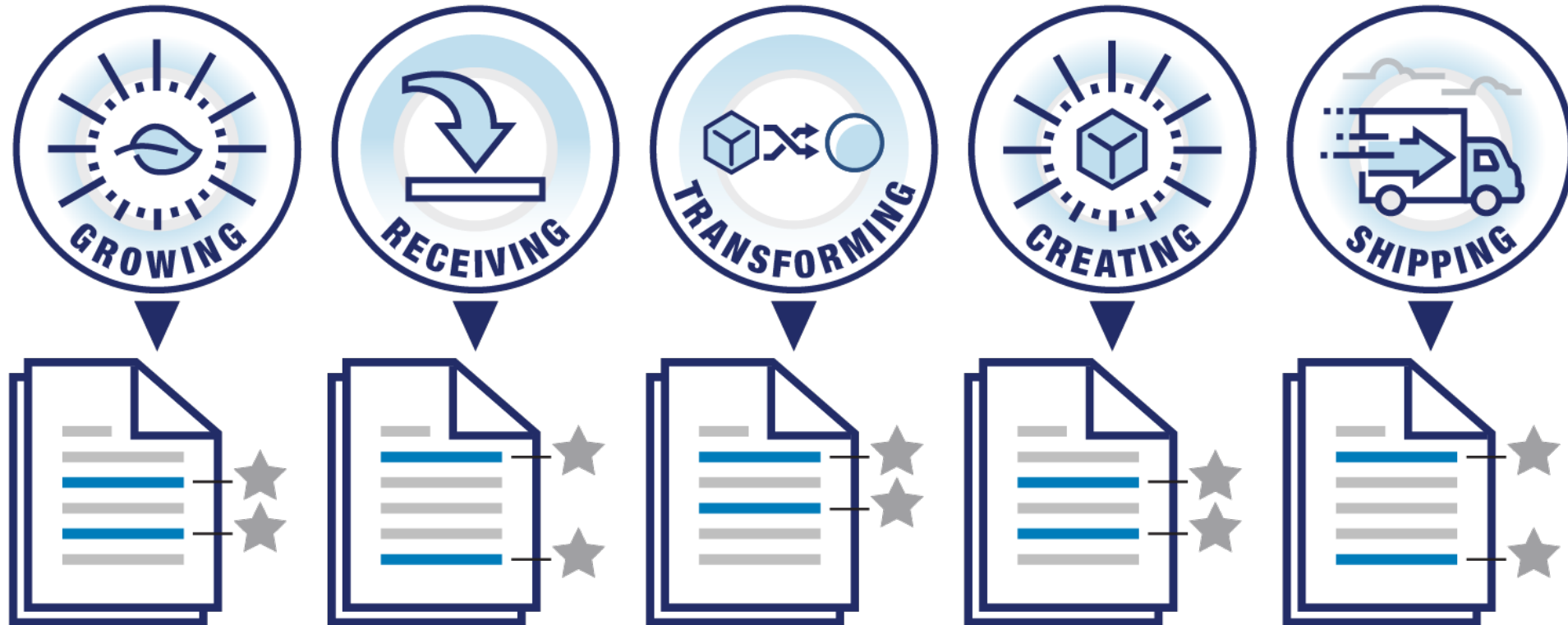
Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

The KDEs required would vary depending on the CTE that is being performed.

The records required at each CTE would need to contain and **link the traceability lot code** of the food to the relevant KDEs.



Critical Tracking Events (CTEs)



Key Data Elements (KDEs)

Establishing and Assigning Traceability Lot Codes



- Traceability Lot Code
 - A descriptor, often alphanumeric, used to identify a traceability lot
 - Important for making linkages within a firm and through a supply chain
 - Along with the information on the traceability lot code generator, helps FDA to quickly go back to the entity within the supply chain that originated, created, or transformed the product
 - Must be linked to KDEs
- Enables FDA to “skip” points that minimally handle the product

§1.1325: Grower KDEs



Traceability lot code linked to:

- Growing area coordinates

**Additional KDEs required for sprout growers*

**Growers must also keep and send Shipping KDEs and Additional Send KDEs for Farms*



§1.1345: Creation KDEs



Traceability lot code of the food created linked to:

- Creation location identifier and description
- Creation completion date
- Traceability product identifier and product description
- Quantity and unit of measure
- Reference record type(s) and #(s) containing Creation KDEs



§1.1340: Transformation KDEs



Traceability lot code of the food produced through transformation linked to:

- Traceability lot code, product identifier and description of food used
- Quantity of each traceability lot of food used
- Transformation location identifier and description
- Transformation completion date
- New traceability product identifier and description
- Quantity and unit of measure of the food produced
- Reference record type(s) and #(s) containing Transformation KDEs



§1.1335: Receiving KDEs



Traceability lot code linked to:

- Immediate previous source location identifier and description
- Entry number (if imported)
- Receiver location identifier and description
- Receipt date and time
- Quantity received and unit of measure
- Traceability product identifier and description of product received
- Traceability lot code generator location identifier, description and POC
- Reference record type(s) and #(s) for documents containing Receiving KDEs
- Transporter name



§1.1350: Shipping KDEs

(Keep and send unless otherwise indicated)

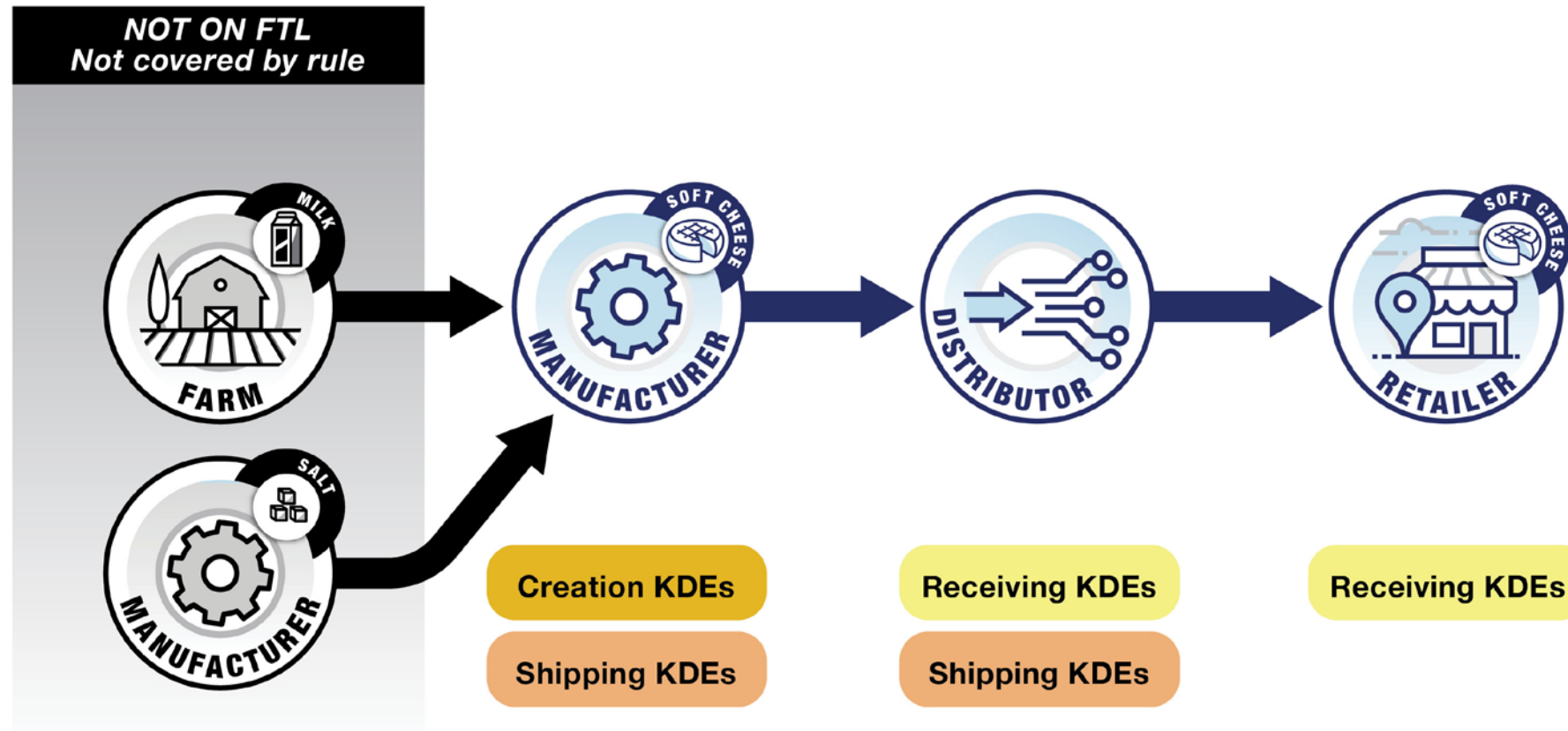
- Traceability lot code(s) for the food
- Entry number(s) (if imported)
- Quantity and unit of measure of the food
- Traceability product identifier and product description
- Traceability lot code generator location identifier, description and POC
- Immediate subsequent recipient location identifier and location description
- Shipping location identifier and description
- Shipment date and time
- Reference record type(s) and #(s) containing Shipping KDEs (keep but do not send)
- Transporter name (keep but do not send)

§1.1315: Traceability Program Records

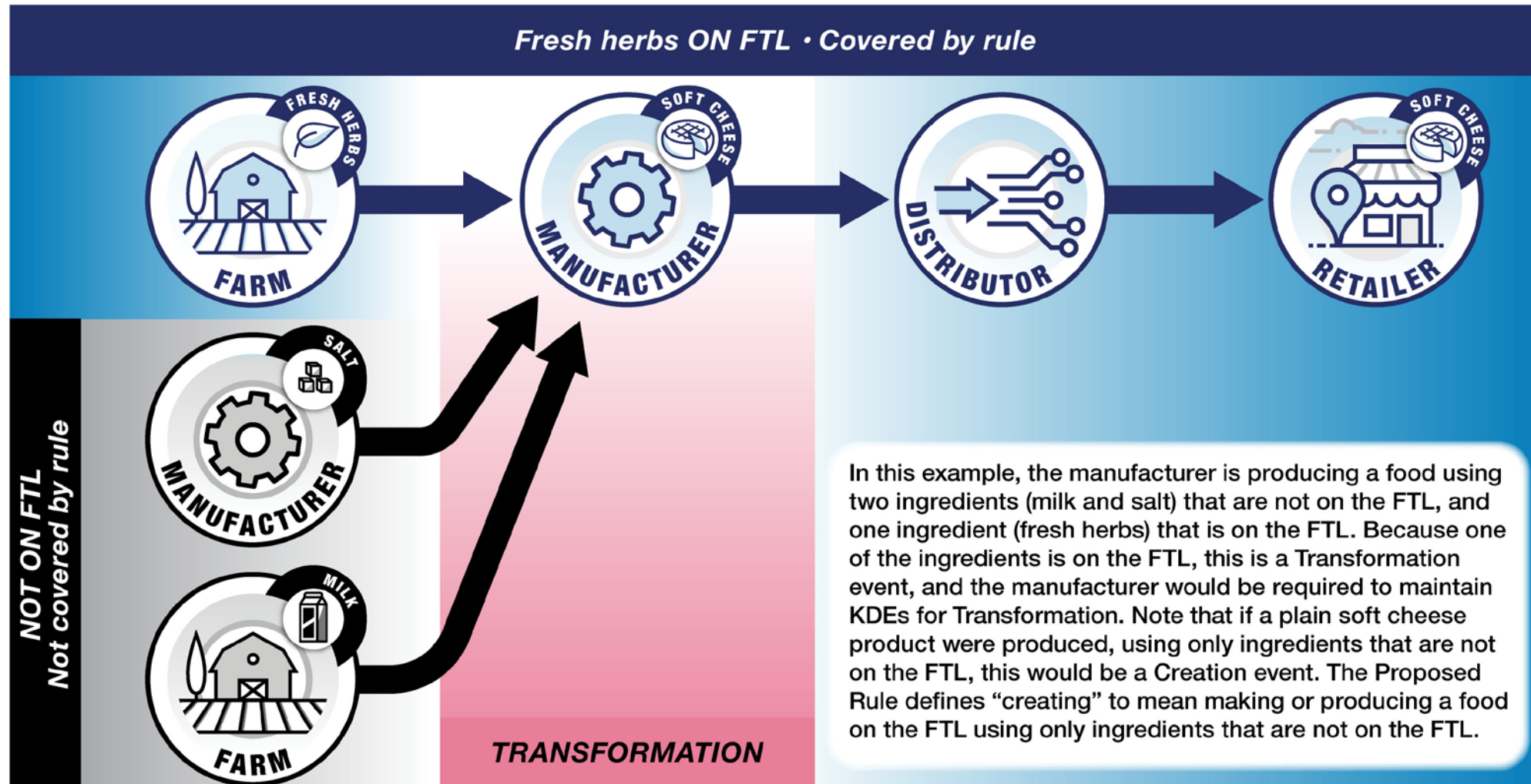


- Records related to a firm's internal traceability program
- Intended to help us more quickly review and understand the information provided by a firm during an investigation into a foodborne illness outbreak involving a food on the FTL
- Records must be maintained for 2 years after discontinuance

Example: CTEs for a Soft Cheese Supply Chain



Transformation – Soft Cheese w/ Fresh Herbs



Generic supply chain example



Program Records

Growing KDEs

KDEs to Send
To 1st Receiver

Originator
Harvester
Cooling
Packing

Shipping KDEs



Program Records

1st Receiver
KDEs

Receiving KDEs

Transformation
KDEs

Shipping KDEs



Program Records

Receiving KDEs

Shipping KDEs



Program Records

Receiving KDEs



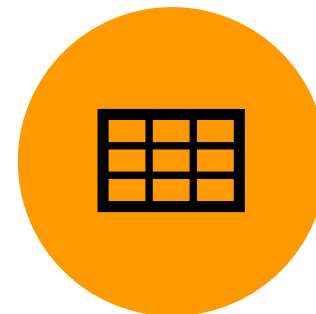
Records maintained as either **original paper records**, **electronic records**, or true copies and stored to prevent deterioration or loss.



Records must be **kept for 2 years** from the date you created the record



Records would have to be made available to FDA as soon as possible, but **no later than 24 hours after a request** is made.



If requested to assist FDA during an outbreak or other threat to public health, the records would need to be provided to FDA in an **electronic sortable spreadsheet**

Additional Requirements

Proposed Requirements

What happens if I fail to comply with the requirements?

- Violation of the recordkeeping requirements is a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.
- An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements have not been complied with regarding such article.

Compliance dates

- If finalized, the rule would become effective 60 days after it is published in the *Federal Register*.
- Compliance date for ***all covered entities*** would be two years from the effective date of the final regulation.

Review of Proposed Rule Key Concepts

- Goal of the proposed rule is to ensure KDEs (especially TLC) can be maintained across the supply chain for more efficient and effective tracing while providing firms flexibility within their existing tracing systems
- We are seeking comments that:
 - Provide examples of business models that may not be compatible with the proposed rule, with an explanation of why
 - Identify and explain if there is confusion within the proposed rule

Resources:

- Three Public Meeting recordings and transcripts [available](#)
- Food Traceability proposed rule [webpages](#)
 - Additional Information:
 - [Food Traceability Proposed Rule At-A-Glance](#)
 - [Food Traceability Proposed Rule Exemptions At-A-Glance](#)
 - [Food Traceability List](#)
 - [Risk Ranking Model for Food Tracing tool](#)
 - [Which Key Data Elements Would Apply to Me?](#)
 - [Who is Subject to the Rule Flowchart](#)
 - [Pre-recorded Webinar to Discuss Food Traceability Proposed Rule](#)
 - [Supply Chain Examples](#)
 - [First Receiver Examples](#)
 - [Creation and Transformation](#)
 - [Webinar/video](#)
- Additional questions related to this rule should be sent to the [FSMA Technical Assistance Network](#)

Thank you!



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