



# Traceability Recordkeeping Under FSMA: What Dairy Processors Need to Know About FDA's Final Rule

Presented By:



#### **IDFA Host**



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#### Presenter



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# Agenda

- Overview and Major Changes
- Scope of the Rule
- Key Data Elements Defined
- Requirements by Critical Tracking Event
- Traceability Program Records
- Recordkeeping and Production Requirements
- Compliance Timeline and Next Steps



#### How did we get here?

- Section 204(d) of the FDA Food Safety Modernization Act (FSMA) requires FDA to:
  - Create a list of designated "high risk" foods; and
  - Establish recordkeeping requirements for facilities that manufacture, process, pack, or hold those foods
    - New recordkeeping would apply in addition to existing one up, one back records requirements under the Bioterrorism Act
- In February 2014, FDA issued a draft approach to identifying high-risk foods and soliciting comments
- In October 2018, two consumer groups sued FDA to compel the agency to implement Section 204(d)
- In a settlement, FDA committed to issue the final rule by November 7, 2022

#### Overview of the Final Rule

- Creates new recordkeeping requirements to facilitate tracing "high risk" foods in the event of a foodborne illness outbreak or recall
- The designated Food Traceability List identifies foods that are subject to additional traceability requirements
- Requires entities that perform certain events in the food supply chain (Critical Tracking Events) to establish and maintain records containing certain information (Key Data Elements) and link that information a traceability lot code
  - Critical Tracking Events = harvesting, cooling, initial packing of raw agricultural commodities, first land-based receiving, transforming, receiving, shipping
- Entities are also required to establish general traceability program records to describe their recordkeeping operations
- FDA requires most entities to provide the agency with an electronic, sortable spreadsheet within 24 hours of request by FDA in certain situations

# Major Changes from the Proposed Rule

- The Food Traceability List (FTL) did not change, but FDA provided clarity through more detailed definitions and in the preamble discussion.
- 2. The mandated general traceability plan requirements were simplified.
- FDA expanded exemptions from compliance with the rule for certain foods and entities.
- FDA expanded the exemption for foods subject to further processing.

- 5. The Critical Tracking Events (CTEs) were adjusted to better reflect industry practices.
- The required **Key Data Elements** (KDEs) were simplified, and privacy concerns were addressed.
- Exceptions to the **electronic**, sortable spreadsheet requirement were created for certain small entities and the record availability expectations were clarified.
- The **compliance date** for the rule was extended to three years and is now **January 20, 2026**.



#### Who and what is covered by the rule?

• Final Rule applies to persons who manufacture, process, pack, or hold foods that appear on the Food Traceability List **OR** foods that contain a listed food as an ingredient, unless an exemption applies

#### • The Food Traceability List includes:

| Cheeses, other than hard cheeses                  | Shell eggs   | Nut butter (does not include soy or seed butters) | Cucumbers (fresh)                          |
|---|--|---|--|
| Herbs (fresh)                                     | Leafy greens (fresh),<br>including fresh-cut leafy<br>greens | Melons (fresh)                                    | Peppers (fresh)                            |
| Sprouts (fresh)                                   | Tomatoes (fresh)   | Tropical tree fruits (fresh)                      | Fruits and vegetables (fresh-cut)          |
| Finfish, including smoked fish (fresh and frozen) | Crustaceans<br>(fresh and frozen)                            | Mollusks, bi-valves (fresh and frozen)            | Ready-to-eat deli salads<br>(refrigerated) |

#### FTL: Cheeses, other than hard cheeses

- FDA clarified that "Cheese, other than hard cheeses" includes:
  - Cheese (made from pasteurized milk), fresh soft or soft unripened (ex. cottage, cream cheese, mascarpone, ricotta, etc.)
  - Cheese (made from pasteurized milk), soft ripened or semi-soft (ex. brie, feta, brick, muenster, etc.)
  - Cheese (made from unpasteurized milk), other than hard cheese
    - "Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, Colby cheese as defined in 21 CFR 133.118, and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.
  - Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged
- In the preamble to the final rule, FDA acknowledged that most cottage cheese produced in the US is regulated under the PMO and is considering whether an exemption would be appropriate

#### Food Traceability List Clarifications

- The final FTL specifies what form foods on the list take
  - If a commodity is listed as "fresh" on the FTL, then only the fresh commodity is covered by the final rule
  - If the form of the food changes so that it is no longer fresh, then the food would no longer be covered
    by the final rule
    - Though the person changing the FTL food would need to keep receiving records
- When a FTL food is used as an ingredient in a multi-ingredient food:
  - When a "fresh" commodity on the FTL is used as an ingredient in a multi-ingredient food, the multi-ingredient food is covered under the final rule (i.e., fresh lettuce in a bagged salad mix or fresh tomato slices in a sandwich)
  - If the ingredient in the multi-ingredient food is not in the form designated on the FTL, the food is not covered by the final rule (i.e., mozzarella on a frozen pizza or trail mix with dried papaya)
  - If the FTL food does not receive a kill step and is not transformed so that it is no longer on the FTL, it is covered by the final rule (i.e., peanut butter in a sandwich cracker that did not receive a kill step)

#### Food Traceability List Clarifications continued...

- Frozen spinach, frozen cut mango, dried peppers, or dried herbs are not covered by the rule
- FTL does not include cheese that is frozen, shelf stable, or aseptically processed and packaged
- FDA specifies that "nut meals and powders," "flours (wheat, rice or soy)," and "flavorings" are separate commodity designations from "nut butters" and therefore are not on the FTL
- "Peanut butter chips" are a separate commodity from "nut butters," but if they are produced using peanut butter as an ingredient without the application of a kill step, the peanut butter chips would be covered by the rule as they contain an ingredient on the FTL

#### Updates to Food Traceability List

- FDA declined to create a process for stakeholders to initiate or request changes to the list
- FDA intends to conduct a review to determine whether it is appropriate to revise the Food Traceability List every five years if resources permit
- To update the list, FDA will publish a notice in the *Federal Register* stating the proposed changes to the list, its reasoning for these changes, and requesting information and views on the proposed changes
- After considering comments, FDA will publish a notice stating whether it is making any changes to the list and the reasons
- FDA will publish the revised list on its website
- Any deletions from the list would take effect immediately, and any additions to the list would become effective 2 years after the publication of the notice, unless otherwise stated

#### What entities are exempt?

#### FDA provides a **complete exemption** for:

- Farms (or the farm activities of farm mixed-type facilities) with respect to the produce they grow, when the farm is not subject to the Produce Safety Rule or farms with no more than \$25,000 in average annual produce sales as calculated under 21 CFR 112.4(a)
- Shell egg producers with fewer than 3,000 laying hens at a farm, with respect to the shell eggs they produce at that farm
- Other producers of RACs (other than produce or eggs) with an average annual monetary value of food sold during the previous 3-year period of no more than \$25,000, on a rolling basis, adjusted for inflation using 2020 as the baseline year for calculating the adjustment
- Food produced on a farm, including food packaged on a farm, when the owner, operator, or agent in charge of the farm sells or donates the food directly to a consumer
- Transporters of food
- Nonprofit food establishments
- Persons who manufacture, process, pack, or hold food for personal consumption
- Certain persons who hold food on behalf of individual consumers (e.g., hotel desk concierge, reception desk staff in an apartment building, staff at an office complex)
- Persons who manufacture, process, pack, or hold foods on the FTL during or after the time the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act, The Poultry Products Inspection Act, or the Egg Products Inspection Act

#### Exemptions for Retailers and Restaurants

- FDA provide a **complete exemption** for small retail food establishments and restaurants where the three-year rolling average of the annual monetary value of food sold or provided is no more than \$250,000
- FDA provides **partial exemptions** for retail food establishments (RFE) and restaurants for:
  - FTL food that is produced (including food produced and packaged on the farm) on a farm and sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm, if the RFE or restaurant maintains a record documenting the name and address of the farm for 180 days
  - FTL food purchases made by one RFE or restaurant from another RFE or restaurant on an ad hoc basis outside the buyer's usual purchasing practice, if the purchasing entity maintains a record documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase

#### What foods are exempt?

- FDA provides a **complete exemption** for the following foods:
  - Food that is produced and packaged on a farm when the packaging remains in place until the food reaches the consumer and the packaging label indicates the contact information for the producing farm
  - \*Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions in Section 112.2(b) of the Produce Safety Rule are satisfied
  - Shell eggs from farms where all eggs produced receive a treatment in accordance with Section 118.1(a)(2) of the Shell Egg Rule
  - Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation program subject to the requirements of 21 C.F.R. § 1240.60 or covered by a final equivalence determination by FDA
  - \*Produce that is identified as rarely consumed raw in 21 C.F.R. § 112.2(a)(1)
  - \*Foods designated for research or evaluation use provided that the food is not intended for retail sale or distribution to the public and is accompanied by the statement "food for research or evaluation use"
  - Commingled RACs other than produce, or those that will become commingled RACs provided there is a written agreement in place

# Treatment of Foods Subject to Further Processing

- FTL foods that undergo a kill step
  - Entity performing the kill step must maintain records of the application of the kill step and EITHER:
    - Receiving records OR
    - A written agreement with the shipper of the food stating that the receiver will apply a kill step
- Foods that are **changed** such that they are no longer on the FTL (e.g., freezing mozzarella on a frozen pizza)
  - Entity performing the change must maintain receiving records
- When it is known early in the supply chain that the food will be subject to a kill step or be changed by another entity (other than by a restaurant, retail food establishment, or consumer) such that the food is no longer on the FTL, the food is exempt from traceability requirements provided there is **a written agreement** between the shipper and receiver stating that that the receiver will apply a kill step or change the food such that it is no longer on the FTL
- Foods to which a kill step already has been applied or that have been changed such that they are no longer on the FTL are exempt from the rule



#### Traceability Lot Codes

- Traceability lot codes are central to the rule's operation
- A **traceability lot code** is a descriptor, often alphanumeric, used to identify a traceability lot
- A **traceability lot** means a batch or lot of food that has been initially packed (for RACs other than food obtained by a fishing vessel), received by the first land-based receiver (for food from a fishing vessel), or transformed.
  - Traceability lot codes can only be assigned at these CTEs, and when a receiver is the first covered entity to handle an FTL food
- The **traceability lot code source** is the place where a food was assigned a traceability lot code
- The **traceability lot code source reference** is an alternative method for providing FDA with access to the location description for the traceability lot code source
  - Examples include the FDA Food Facility Registration Number or a web address that provides FDA with the location description for the traceability lot code source
- At each Critical Tracking Event, entities would be required to link the traceability lot code to Key Data Elements

## Changes to Key Data Elements (KDEs)

- No "physical location name" as this is captured in the "location description."
- "Product description" simplified to eliminate the elements of "category code/term" and "category name" and to require the "brand name, commodity, and variety" "if applicable."
- Providing a "point of contact" to others in the supply chain is no longer required, but contact information for someone familiar with an entity's traceability program must be identified in the program documents. This can be by title or position, rather than a specific individual.
- "Traceability lot code generator" replaced with "traceability lot code source" to highlight the importance of the physical location where the traceability lot code was assigned rather than the person who assigned the code; use of "traceability lot code source reference."
- For shippers and receivers, no longer need the entry number for imported foods, the time of shipping or receiving, and the name of the transporter.
- FDA eliminated the definition of a "lot" for the purposes of the traceability rule, allowing covered entities to determine the lot for an FTL food.



## New Critical Tracking Events (CTEs)

- The final rule identifies seven CTEs: harvesting, cooling, initial packing of a raw agricultural commodity, first land-based receiving, transforming, shipping, and receiving
  - Traceability lot codes must be assigned at the initial packing, first land-based receiving, and transforming CTEs
  - The rule also notes that a receiver who is the first covered entity to handle a food would need to assign a traceability lot code
- Initial packing of an RAC and the first land-based receiving CTEs are designed to help eliminate the confusion and burden associated with the proposed rule's "first receiver" CTE
  - Initial Packing is defined as packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time
  - First Land-Based Receiving is defined as the person taking possession of a food for the first time on land directly from a fishing vessel

## **Critical Tracking Events**

- The CTEs for which recordkeeping is required are:
  - Harvesting
  - Cooling
  - Initial Packing of Raw Agricultural Commodities
  - First Land-Based Receiving
  - Transformation
  - Shipping
  - Receiving

#### Harvesting

**Harvesting** means the activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food

#### Recordkeeping requirements include:

- 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
- Date of harvesting

Reference document type and reference document number

For Piolice/aquacultured food:

- Name of the field or other growing area (or container) from which the food was harvested (must correspond to the name used by the grower)
- Other information identifying the harvest location at least as precisely as field or growing area name

The listed KDEs, except the reference document type and number, must be provided to the initial packer along with the harvester's business name and phone number

# Cooling (before initial packing)

**Cooling** means the active temperature reduction of a raw agricultural commodity Recordkeeping requirements include:

- 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 where the food was cooled
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

The listed KDEs, except the reference document type and number, must be provided to the initial packer

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# Initial Packing (RAC)

**Initial Packing of RACs** means the packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time

#### Recordkeeping requirements include:

- Commodity and, if applicable, variety of the food received
- Quantity and unit of measure of the food received and date of receipt
- Location description for the farm where the food was harvested and harvesting date
- For Produce/aquacultured food:
  - Name of the field or other growing area/container from which the food was harvested (must correspond to the name used by the grower)
  - Other information identifying the harvest location at least as precisely as field or growing area name/container
- Business name and phone number for the harvester of the food

Location description for where the food was cooled and date of cooling (if applicable)

Traceability lot code assigned by the initial packer

P oduc d cription of the packed food

Quanty amount of measure of the packed food and date of initial packing

- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Reference document type and reference document number

All of the listed KDEs must be linked to the traceability lot code assigned at this CTE

#### First Land-Based Receiver

**First Land-Based Receiver** means the person taking possession of a food for a first time on land directly from a fishing vessel

#### Recordkeeping requirements include:

- Traceability lot code assigned by the first
   land-based receiver
- Species and/or acceptable market name for unpackaged food, or the product description for packaged food
- Quantity and unit of measure of the food
- Harvest date range and locations for the trip during which the food was caught

- Location description for the first landbased receiver (i.e., traceability lot code source) and (if applicable) traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number

All of the listed KDEs must be linked to the traceability lot code assigned at this CTE

#### Receiving

**Receiving** refers to an event in a food's supply chain when food is received by someone other than a consumer after being transported from another physical location, including intracompany shipments

#### Recordkeeping requirements include:

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Date the food was received
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

\* When food is received from a person who is exempt from the rule; the receiver must assign a traceability lot code if one has not been already been assigned (does not apply to RFEs or restaurants) and maintain the same receiving KDEs

\*All of the listed KDEs must be linked to the traceability lot code previously assigned

#### **Transformation**

**Transformation** means an event in a food's supply chain that involves manufacturing/processing a food or changing a food or its packaging, when the output is on the Food Traceability List

#### Recordkeeping requirements include:

For FTL foods used as ingredients-

- Traceability lot code for the food
- Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

For new FTL foods produced-

- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source), and (if

applicable) the traceability lot code source reference

- Date transformation was completed
- Product description for the food
- · Quantity and unit of measure of the food
- Reference document type and reference document number

\* For RACs and sprouts that are not initially packed before transformation, the transformer must maintain initial packer KDEs

All of the listed KDEs must be linked to the traceability lot code assigned at this CTE.

\* Transformation does not apply to retail food establishments and restaurants with respect to foods they do not ship (foods they send or sell directly to consumers)

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# Shipping

**Shipping** refers to an event in a food's supply chain where it is transported from one physical address to another, including intercompany shipments

Recordkeeping requirements include shippers maintain and provide:

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from

which the food was shipped

- Date the food was shipped
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

All of the listed KDEs must be linked to the traceability lot code previously assigned

Shipping KDEs do not apply to the shipment of food that occurs before the food is initially packed

## **Cross-Docking Considerations**

- FDA clarifies that records must be kept regarding both locations where the shipping event began and the location where it ended, but it is not necessary to have records of the route the food took or instances where it may have been moved from one carrier to another
- In situations where food is arranged for transport from point A to B but is briefly placed on a loading dock at point X in order to be transferred from one truck to another, the food would not be considered shipped to point X and no records would need to be kept regarding point X
- To determine whether a food is considered received at point X, FDA would consider factors such as:
  - How long the food was held at point X
  - Whether it was there under temperature-controlled conditions different than the transportation conditions
  - Whether it was taken into inventory

## **Direct Store Delivery Considerations**

- The retail food establishment has "received" food, as that term is used in the regulations (regardless of whether it has been taken into inventory) and responsible for receiving KDEs
- The DSD vendor could maintain the receiving records on behalf of the retailer
- The retailer would need to ensure the records could be retrieved in 24 hours of a request from FDA



# Traceability Plan

- A roadmap of your program and where things are located
- Your traceability plan must include:
  - Description of the procedures you use to maintain the required records, including the format and location of the records
  - Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack, or hold and how you assign traceability lot codes to foods on the FTL, if applicable
  - Description of how you assign traceability lot codes
  - Statement identifying a point of contact for questions regarding your traceability plan and records
  - If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods, including the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
- You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are compliant with the rule
- You must retain your previous traceability plan for 2 years after you update the plan



# Recordkeeping Requirements

- Records required under the rule must be maintained for 2 years from the date they were created
- Offsite storage of the records is permissible, provided the records can be made available to an FDA representative no later than 24 hours after a request
  - Electronic records are considered onsite if they are accessible from an onsite location
- Electronic records may include electronic links
- Records also can be required to be provided in English within a reasonable time if they are maintained in a language other than English
- Covered entities may enter into agreements with individuals or firms to create and keep the records required by the rule on their behalf
- No need to create duplicate records; or maintain information in a single set

# Record Availability and Format

- All records must be made available within 24 hours of a request (or a reasonable time to which FDA has agreed)
  - Can be made during routine inspection
  - May also need to provide coding, glossary, explain abbreviations, how information corresponds
- The final rule requires entities to provide records to FDA within 24 hours (or a reasonable time to which FDA has agreed) in an electronic, sortable spreadsheet for specified foods and date ranges when requested by FDA in certain situations
  - Providing information in this format is required when necessary to help FDA prevent or mitigate a
    foodborne illness outbreak; to assist in the implementation of a recall; to otherwise address a threat to
    the public health, including situations where FDA has a reasonable belief that a food presents a
    SAHCODHA hazard
  - Request may be made by phone, and in writing upon request

# Exemptions to Electronic Spreadsheet Requirement

- Three types of entities are exempt from this requirement:
  - (1) farms with a three-year rolling sales average of no more than \$250,000,
  - (2) retail food establishments and restaurants with a three-year rolling sales average of no more than \$1 million, and
  - (3) persons other than a farm, retail food establishment, or restaurant whose three-year rolling sales average is no more \$1 million



# Establishing New Modified Requirements and Exemptions

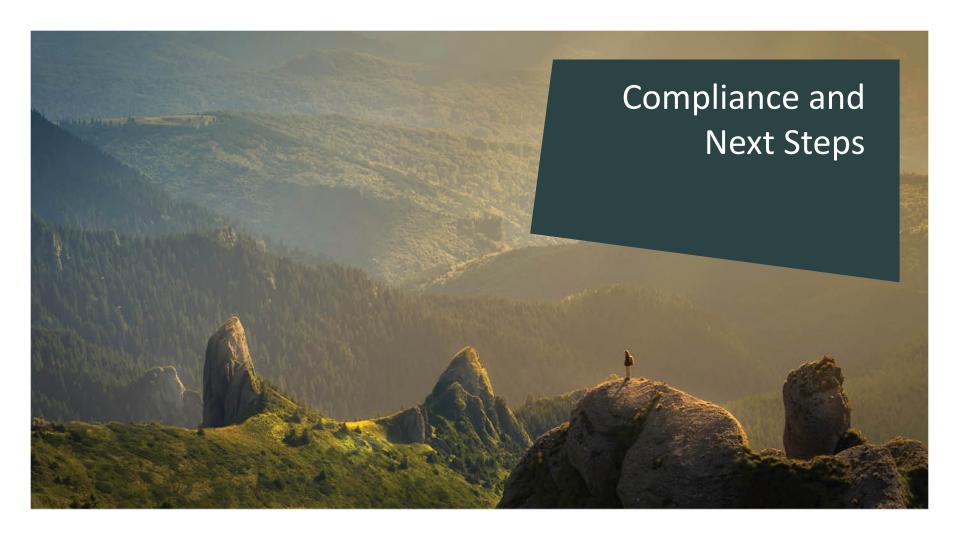
- FDA could modify the requirements or exempt a food or type of entity from the rule's requirements if the agency determines the application of the rule is not necessary protect the public health
  - FDA could act on its own initiative or in response to a citizen petition submitted by an interested party
- Even when modified requirements or an exemption would apply, entities required to register with FDA would be required to keep one up, one back records under the Bioterrorism Act regulations
- The final rule lays out procedures for requesting, revising or revoking modified requirements or exemptions when such action is necessary to protect the public health

# Waivers for Economic Hardship

- FDA could waive one or more requirements for an individual entity or type of entity if the agency determines that:
  - The application of the requirement would result in an economic hardship, due to the unique circumstances of the individual entity or type of entity;
  - The waiver will not significantly impair FDA's ability to identify recipients of food and prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequence or death resulting from an adulterated or misbranded food; and
  - The waiver would not otherwise be contrary to public interest
- Merely having relatively low revenue or relatively few employees would not ordinarily constitute an economic hardship sufficient to qualify for a waiver

# Waivers for Economic Hardship, continued...

- FDA could issue a waiver either on its own initiative, in response to a written request (for an individual entity), or in response to a citizen petition (for a type of entity)
- FDA could modify or revoke a waiver if it determines:
  - Compliance with the waived requirement would no longer impose a unique economic hardship;
  - The waiver could significantly impair the agency's ability to identify recipients of a food to prevent or mitigate a foodborne illness outbreak; or
  - The waiver is otherwise contrary to the public interest
- FDA might become aware that the circumstances under which it had granted a waiver to a firm had changed through a routine inspection or an inspection in the course of an investigation into a foodborne illness outbreak
- The final rule lays out procedures for waivers



# Compliance Date

FDA has determined that the compliance date for all covered entities will be 3 years after the effective date of the final regulations on January 20, 2026

### Enforcement

- Any violation of the recordkeeping requirements of the Proposed Rule would be a prohibited act under Section 301 of the FFDCA, except when committed by a farm
- For imported foods, if it appears that the recordkeeping requirements have not been complied with for a particular food, that food would be subject to refusal of admission under Section 801(a)(4) of the FFDCA
- Note: FDA makes clear in the preamble that the rule to applies to foreign entities

# Conduct a Gap Assessment

#### Template for Traceability Case Study Data Prepared by Hogan Lovells US LLP Last updated 1/4/2021 Introduction: This document provides a template to assist companies in determining what information they may be required to maintain or send to customers or provide to FDA under the Proposed Food Traceability Rule. To ensure you have as accurate an assessment as possible, we recommend completing this template for a variety of foods representative of your product portfolio. Instructions: Identify a food that you manufacture, process, pack, or hold that is or contains a food on the Food Traceability List (provided on the "Food Traceability List" tab). You may also conduct this exercise with foods not on the Food Traceability List to assess potential impact should new foods be added Determine whether the food qualifies for one of the proposed exemptions (see the "Exemptions" tab for some of the most common exemptions). 3 Identify the Critical Tracking Events (CTEs) (i.e., receiving, transforming, creating, shipping, first receiving, originating (e.g., growing)) for the product you are tracing. For each CTE you are involved in, complete the template for the corresponding tab in this document by reviewing your existing records for the food to determine to what extent the required data already is maintained. In the "data element" column, provide an example of the corresponding data element for the food you are tracing in your case study. Note: For foods subject to transformation you may have multiple incoming foods on the Food Traceability List that are combined to make a single food (e.g., a blend of shredded cheese). Use the outcome to identify gaps in data, to determine whether data can be used to produce a sortable, electronic spreadsheet, and to inform possible comments to FDA. Note: The rule requires the KDE's to be linked to the traceability lot code.

# Questions?



# **Contact Information**



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# QUESTIONS?





# Thank you for joining us.

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