



IDFA

**International
Dairy Foods Association**

Complying with FDA's Traceability Rule: Potential Challenges and Considerations

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- Food Traceability Final Rule: Background & Summary of Requirements
- Compliance & Enforcement
- Potential Congressional Action to Delay Compliance
- Compliance Challenges
- Partnership for Food Traceability



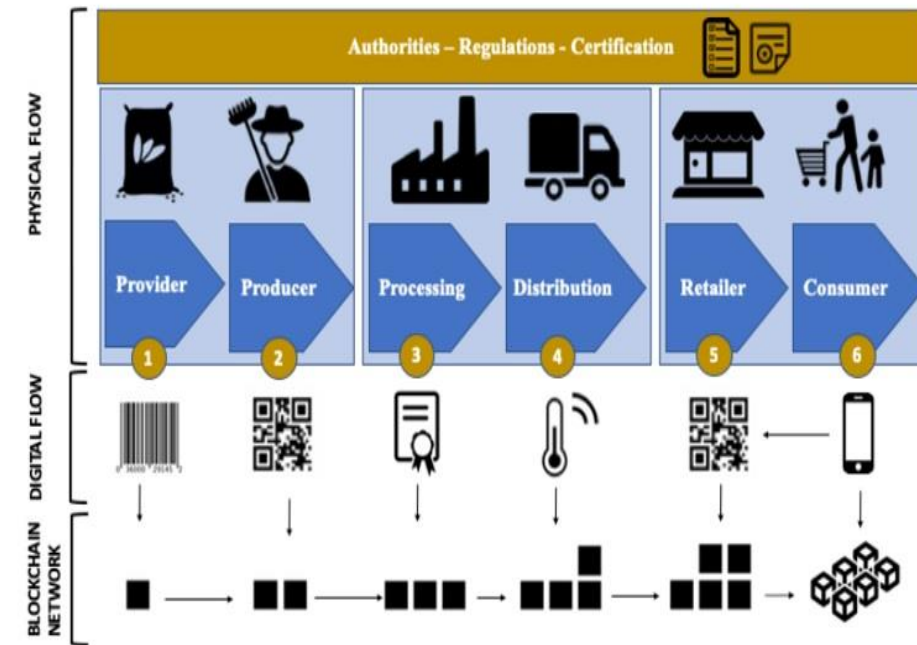
FSMA Section 204: Enhancing Tracking/Tracing of Food & Recordkeeping

- FDA more rapidly/effectively identify foods causing/with potential to cause human illness, remove from marketplace, prevent illnesses
 - Root cause investigation initiated sooner, more likely to identify contributing factors, can better target corrections
- FSMA directed FDA to:
 - Designate a list of “high-risk” foods subject to additional recordkeeping
 - Establish recordkeeping requirements for entities that manufacture, process, pack or hold those foods
 - Must be “scale–appropriate & practicable for facilities of varying sizes and capabilities”
 - In addition to regulations issued under Bioterrorism Act
- FSMA limits FDA’s ability to require:
 - Specific technologies
 - Full pedigree for a food
 - Records beyond the immediate subsequent recipient
 - Case level tracking



Food Traceability Final Rule Requirements

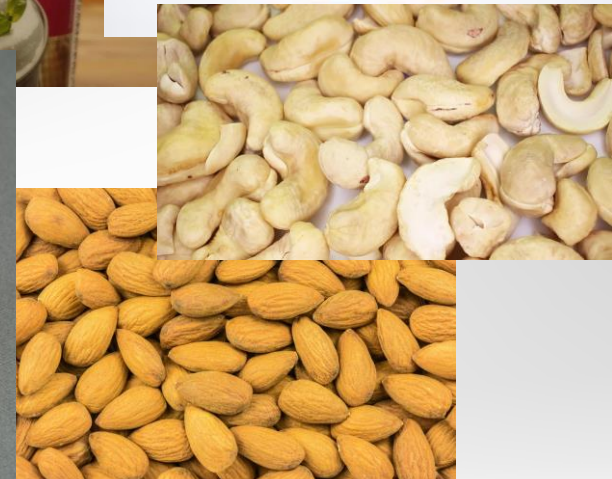
- Creates record keeping requirements for foods on **Food Traceability List (FTL)** to assist FDA trace foods during outbreaks, recalls, other threats to public health
- Identifies **Critical Tracking Events (CTEs)** along supply chain where records containing **Key Data Elements (KDEs)** must be established, maintained, shared with subsequent receiver of the food
- Records linked through **Traceability Lot Codes (TLCs)**
- Firms must establish/maintain **traceability plan**, describing how they will comply with final rule requirements
- Firms must supply records to FDA **within 24 hours** of request; most must provide an **electronic sortable spreadsheet**
 - **FDA can examine required records during routine inspections**
- **Legal consequences for failure to comply**



Scope of Food Traceability Final Rule

Who is subject to the rule?

- “Persons” who manufacture, process, pack or hold foods on FTL
 - Applies to firms beyond registered facilities, including farms & retail/restaurants
- Covers entire food supply chain, unless an exemption applies
- Includes foreign & domestic firms
- Covers food on FTL & foods that contain a FTL food as an ingredient, provided the FTL food remains in same form (e.g., fresh) as it appears on the FTL





Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened

Cheese (made from pasteurized milk), soft ripened or semi-soft

Cheese (made from unpasteurized milk), other than hard cheese

Shell eggs

Nut butters

Cucumbers (fresh)

Herbs (fresh)

Leafy greens (fresh)

Leafy greens (fresh-cut)

Melons (fresh)

Peppers (fresh)

Sprouts (fresh)

Tomatoes (fresh)

Tropical tree fruits (fresh)

Fruits (fresh-cut)

Vegetables (fresh-cut)

Finfish (histamine-producing species) (fresh and frozen)

Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen)

Finfish, species not associated with histamine or ciguatoxin (fresh and frozen)

Smoked finfish (refrigerated and frozen)

Crustaceans (fresh and frozen)

Molluscan shellfish, bivalves (fresh and frozen)

Ready-to-eat deli salads (refrigerated)

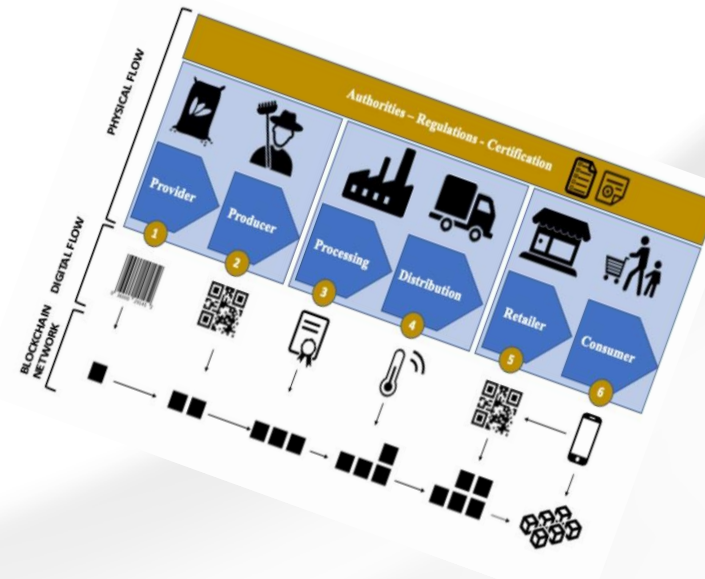
FDA Food Traceability List (FTL)

- Additional Recordkeeping for FTL Foods

- Dairy: semi soft & soft cheeses; yogurts & ice cream w/tree nut/peanut butter inclusions
- FDA plans to exempt certain types of cottage cheese from the FTL
- FTL updated at a minimum of every 5 years, more frequently if data supports
 - Final rule effective date, January 20, 2023; FTL update, January 20, 2028

- IDFA commissioned University of Wisconsin study to assimilate data to provide to FDA to inform semi soft & soft cheeses to include/exclude on FTL

- 200 plus studies (published and unpublished); assimilate factors that impact pathogen survival/growth in standardized cheeses (pH, aw, NaCl, organic acids, cultures, etc.)
- Anticipated completion date, 5/29/2025



Critical Tracking Events (CTEs)

21 CFR 1.1325 et seq.

- CTEs are key activities along the supply chain for which Key Data Elements must be created, maintained, and/or shared
- The final list of CTEs includes:
 - Harvesting
 - Cooling (before initial packing)
 - Initial Packing (of raw agricultural commodities)
 - First Land-Based Receiving
 - Shipping
 - Receiving
 - Transforming
- One entity can perform more than one CTE
- Certain CTEs require assigning a TLC



Key Data Elements (KDEs) 21 CFR 1.1325 et seq.

- **KDEs:** information associated with a CTE for which a record must be established, maintained and/or shared with subsequent receiver of the food
- **KDEs:** vary at each CTE but records will contain information needed to effectively trace a product based on CTEs a firm performs
- **Reference Documents:** business transaction documents, records, messages, in electronic or paper form, that contain some/all KDEs for a CTE
 - May be established by you or obtained from another person
 - Can include bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, receipts
 - Reference document numbers assigned to reference documents



REPLACE WITH YOUR LOGO				
[Company Name]	[Address]	[City, State, Zip Code]	[Phone]	[Website]
Vendor Information	[Name]	[Address]	[City, State, Zip Code]	[Phone]
[Address]	[City, State, Zip Code]	[Phone]	[Website]	
Customer Information	[Name]	[Address]	[City, State, Zip Code]	[Phone]
[Address]	[City, State, Zip Code]	[Phone]	[Website]	
Item #	Description	Unit Price	Quantity	Total
			Subtotal	
			Shipping	
			Tax	
			Other	
			Total	
Signature of Authorized Person				
[Title]				
Notes:				

Traceability Lot Code (TLC)

- TLC: a descriptor, alphanumeric, that uniquely identifies a traceability lot within records of traceability lot code source
 - All KDEs must be linked to traceability lot for food
 - Final rule offers flexibility on how TLCs are created/assigned
 - Can only be assigned at certain CTEs
- TLC Source: an entity that assigned a TLC to the food
- TLC Source Reference: an alternative method to provide the TLC Source information, examples include:
 - FDA Food Facility Registration Number for TLC Source
 - A web address with location description for TLC Source



- Purpose of plan: To help FDA review/understand traceability information provided by a firm under the rule
- All persons covered by rule must establish a traceability plan that includes a description of:
 - Procedures used to maintain required records, including format/location of the records
 - Procedures used to identify foods on FTL that a firm manufactures, processes, packs, holds
 - How a firm assigns traceability lot codes to foods on the FTL, if applicable
 - A statement identifying a POC for questions regarding traceability plan & records
 - A farm map showing areas in which a food is grown or raised
- Traceability plans must be update to reflect current practices/compliance
 - Previous traceability plans must be retained for **two years** following an update to the plan

Routine Recordkeeping Requirements

21 CFR 1.1455

- Final rule requires maintenance of legible records stored to prevent deterioration or loss
 - Records may be stored on original paper or electronically with hyperlinks
- Records must be made available within 24 hours of a request by FDA
- Records must be kept for 2 years
- Records can be kept in any language, but must be translated upon request within a reasonable time, as agreed to by FDA
- Another entity may establish/maintain your records if they can be retrieved within 24 hours of an FDA request



Outbreaks & Electronic Sortable Spreadsheets



Requested by FDA for foodborne outbreaks, recalls, other threats to public health

- During a food safety event, records must be provided to FDA in an electronic, sortable spreadsheet unless firm is subject to a partial exemption from that requirement
- FDA may issue a phone request for an electronic, sortable spreadsheet/records

This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403.BIUB:12OCT2020	50 CASES	CHARLES CHEESE CO. BRAND FETA CHEESE 10 x 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	FFRN:456456	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, <u>TLC</u> ville, MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	https://fd.gs1.org/01/11411411411402/10/FPP16-092420	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	https://fd.gs1.org/01/11411411411401/10/FPP16-092120	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	<u>FreshFish</u> BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	<u>FreshFish</u> Importer Inc.	Distro Foodservice DC #45	9/22/2020	https://fd.gs1.org/01/22322322322302/10/FFI2020-09-20	BOL 22302

*See Master Data Spreadsheet for full location descriptions

Key Exemptions, 21 CFR 1.1305

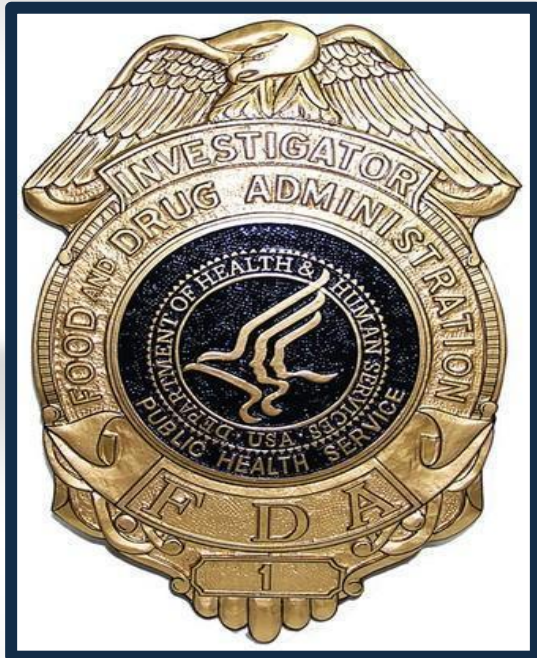
- The final rule includes full & partial exemptions based on:
 - Type of entity (e.g., transporters, fishing vessels, USDA regulated entities are exempt
 - Restaurants/retail establishments are subject to the rule, with some exemptions for these entities to accommodate business practices
 - Type of food (e.g., certain molluscan shellfish, co-mingled RACs (not fruits & vegetables are exempt)
 - Size of entity (e.g., certain small farms & egg producers exempt)
 - Types of processing (e.g., food that is further processed to include a “kill step” is exempt)
- FDA has provided a tool to assist businesses determine if an exemption applies



EXEMPT

Compliance Dates & Enforcement

- **Final Rule:** November 21, 2022
- **Effective Date:** January 20, 2023
- **Compliance Date:** January 20, 2026
 - Single compliance date to ensure the rule's effectiveness.



- Consequences for Non-Compliance, see 21 CFR 1.1460
- Failure to comply is Prohibited Act under section 301(e) of FD&C Act
 - Warning letter to prompt voluntary compliance; Posted on FDA's website
 - Enforcement action if no voluntary compliance; injunctions/seizures
- Failure to comply can result in refusal of admission at import under section 801 of the FD&C Act
 - Import alert posted on FDA's website

- Work in Progress
 - Will work with state/local regulatory partners to enforce
 - “Educate before and while we regulate” approach
- Routine Inspections (potentially remote) will not begin until 2027
 - Will request review of traceability records
 - Will issue a Form 483 with inspectional observations, as needed
 - Response within 15 business days
 - Subject to FOIA, with redactions for confidential information
- ***All covered entities must comply by January 20, 2026***



OVERSIGHT

- **IDFA participated in panel discussions**
 - Association of Food and Drug Officials
 - North America Food Safety and Quality Forum
- **IDFA participated in industry roundtable discussions**, Regan Udall Foundation (RUF) for FDA
 - Report published [Food Traceability cover page \(US Letter\)](#) (reaganudall.org)
 - Public meeting Oct 7

Challenges

- Lack of awareness of requirements
- Processors must request information from suppliers & will receive it in different formats/ways **AND** processors must fill data requests received from distributors, retailers, restaurants in inconsistent ways, **very challenging**
- No standardized naming conventions for food throughout supply chains, lack of agreed upon data carrier (2-D barcodes?), lack of interoperable systems to transfer/receive required data elements
- While distribution centers could provide FDA with a limited number of potential TLCs when a spreadsheet is requested, they can't get to just one TLC without costly investments; is it worth the ROI
- Application of traceability requirements will vary
 - **Some retailers signaling they will want traceability information from suppliers for all foods, not just FTL foods**

Partnership for Food Traceability (PFT)



- *“A public-private partnership between FDA, state officials, and all sectors of the food industry that facilitates implementation of interoperable electronic food traceability systems while maintaining the flexibility to accommodate alternate traceability methods for small businesses ”*
- Brings all parts of supply chain together to make critical implementation decisions & define a shared industry vision for food traceability in collaboration with FDA, state/ local officials
- Brings all traceability efforts into a single overarching vision, without disrupting progress in various sectors

PFT to Deliver

- Common vision for traceability across sectors, industries, associations, consortia
- Forum for technical implementation discussions between industry & FDA
- Consistent set of business & functional requirements for traceability providing clarity to solution providers & ensuring solutions fully meet business needs
- Decision-making mechanism for critical questions of how traceability should be implemented
- Organized public-private plan for how the industry will migrate to enhanced traceability



H.R. 7563 - Food Traceability Enhancement Act



- Sponsors: Reps. Scott Franklin (R-FL-18) & Sanford Bishop (D-GA-2); 18 cosponsors, bipartisan support; Introduced in House 3/2024
- Would remove requirements for restaurants, retail establishments, certain warehouses for maintaining/providing to FDA or others TLC information
- Would require FDA to complete 9 pilot projects for different FTL products that include restaurants, retail food establishments & warehouses distributing to retail food establishments and restaurants to:
 - Measure effectiveness of outbreak investigations conducted w/o traceability lot code information
 - Identify/evaluate the feasibility & effectiveness of low-cost food tracing technologies
- Within 18 months of legislation passing, FDA to submit a report to Congress of pilot findings & recommendations
- Would move out compliance date for final traceability rule at least 2 years

FDA Resources for Food Traceability Rule Compliance

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>

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