FSMA Traceability Rule: Supplemental Slides for Grower Outreach

Produce Safety Educator's Call #63

December 19, 2022

Instructions

- All participants are muted.

- There will be time for questions and discussion at the end of the meeting.

- Feel free to use the chat box to ask questions as well!

- This session will be recorded and the presentation will be shared via the listserv and on our website after the call.

- The views and opinions expressed in this presentation are those of the speakers and do not necessarily reflect legal advice, views or positions of the PSA and its members, nor any entities they represent.

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Agenda for Today

- Introductions

- Preview draft FSMA Traceability Rule supplemental slides

- Discuss the supplemental slides content/provide input to finalization

- A brief toast to the new year, and other PSA updates

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PSA Supplemental Slides: This is new to all of us

- PSA does not yet have a complete understanding of all aspects of the Traceability Rule
  - Draft slides may be adapted based on today's conversation
- This presentation is meant to be a preview, to obtain further feedback from educators and other partners, & keep the conversation/materials moving forward
- Based on feedback, final slides will be posted to the PSA website for use as soon as possible

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FDA Representative

- Welcome Angela Fields, representing FDA

- Angela will help address questions about the Food Traceability Rule

  – Important: FDA has not reviewed or approved the PSA Draft Supplemental Slides

  – FDA has provided two industry-wide briefings

    - Stakeholder Call 15 November, 2022: https://www.youtube.com/watch?v=iEF0hRk19Ho

    - Webinar 07 December, 2022: https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-food-traceability-final-rule-12072022

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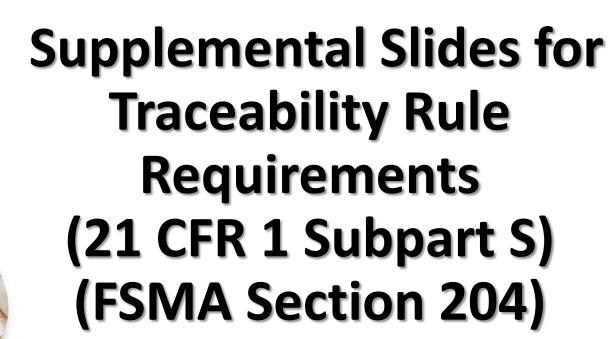# **Preview: Input on the Supplemental Slides**

We will ask these questions at the end, so keep in mind

- What is needed in these supplemental slides?
  - For Module 7
  - For use providing updates to farm-oriented audiences

- Is there anything missing?
  - Keep in mind, this is not a comprehensive slide set

- Should anything be adjusted?
  - From the farm (growing or packing) perspective

Additional Traceability Records for Certain Foods   DRAFT

- Final Rule published November 21, 2022
- Compliance date for all entities is January 20, 2026
  - 3 years after the effective date of the Final Rule
  - Effective date is January 20, 2023
- **These slides summarize selected points that may be important to produce growers**

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www.govinfo.gov/ content/pkg/ FR-2022-11-21/pdf/2022-24417.pdf

® Rule

Requirements for Additional Traceability Records for Certain Foods

A Rule by the Food and Drug Administration on

SUPPLEMENTAL MATERIAL

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DRAFT

Supplemental Slides for Traceability Rule Requirements (21 CFR 1 Subpart S) (FSMA Section 204)

SUPPLEMENTAL MATERIAL

Version: 12/14/2022

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Requirements for Additional Traceability Records for Certain Foods

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Coverage and Exemptions Relevant to Farms

DRAFT

- Persons who manufacture, process, pack, or hold foods that appear on the Food Traceability List are covered

- Exemptions mirror various Produce Safety Rule exemptions and exclusions but there is no "qualified exemption"
  - Farms with a PSR qualified exemption may be required to provide traceability information to their non-qualified end users

- Food packaged on the farm may be exempt from the Traceability Rule
  - Packaging must adequately protect against contamination and remain intact all the way to the consumer

- There are provisions for waivers to the Traceability Rule
  - FDA will waive a requirement on their own initiative or in response to a written request from an individual entity or a citizen petition

- FDA Exemptions and Exclusions tool https://collaboration.fda.gov/tefcv13

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Specific Foods Covered

- Produce and other commodities on the "Food Traceability List"

- Fresh produce items on the list include all types or varieties if covered by the Produce Safety Rule:

Cucumbers	Melons*	Tomatoes
Fresh herbs	Peppers	Tropical tree fruits**
Leafy greens	Sprouts	Some other processed, minimally processed, and non-produce items

* Such as cantaloupe, honeydew, watermelon, etc.

** Includes mango, papaya, mamey, guava, lychee, jackfruit, starfruit, etc. Does not include avocado, citrus fruit, produce that is not a tree fruit (e.g. banana, pineapple, date), tree nuts, or coconut

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New Definitions (short list)

- **Food Traceability List** (FTL) is the list of foods covered under the FSMA Traceability Rule

- **Critical Tracking Events** (CTE) include:
  - Harvesting
  - Cooling (before initial packing)
  - Initial packing
  - Shipping
  - Receiving
  - Transformation

- **Traceability Lot Code** (TLC) identifies each lot of produce

- **Initial Packing** is the step where the TLC is assigned for Raw Agricultural Commodities (RAC) on the FTL

- **Key Data Elements** (KDE) are records related to a CTE that must be created and maintained; some follow the product

- **Location Description** includes the business name, phone, and the location (address or GPS) of the CTE

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Required: Traceability Plan

- Procedures used to identify covered foods
  - Commodities on the Food Traceability List (FTL)
  - Activities: manufacture, process, pack, or hold
- Description of how traceability lot codes are created
- For farms, a farm map showing where foods are grown
  - Location and name of each field, including GPS and other necessary location information
- Point of contact for the traceability plan
- Procedures for maintaining records

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Required: Traceability Lot Code (TLC) for RACs on the FTL

- For raw agricultural commodities (RACs) on the Food Traceability List (FTL)
  - The initial packer assigns the TLC to the traceability lot
  - The Traceability Rule does not provide specific requirements for the form of the Traceability Lot Code, other than the definition
- The TLC links Critical Tracking Events (CTEs), including harvesting, cooling before packing, initial packing, and any other events prior to reaching the consumer, for a lot
  - Recorded information is referred to as Key Data Elements (KDEs)
  - KDE requirements are described in the next two slides

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Required: Traceability Records

- Critical Tracking Events before initial packing are obtained by the initial packer to document the Traceability Lot

Critical Tracking Events (CTE)	Key Data Elements (KDE)		
Harvest	– Location description of farm – Location description of recipient – Name of the field harvested	– Reference document # – Commodity harvested – Date of harvest – Amount harvested	
Cooling (before initial packing)	– Location description of cooler – Location description of recipient – Location description of farm	– Reference document # – Commodity cooled – Date of cooling – Amount cooled	

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Required: Traceability Records (continued)

Once the Traceability Lot Code is assigned, it is passed forward to the next recipient in the chain and connects CTEs

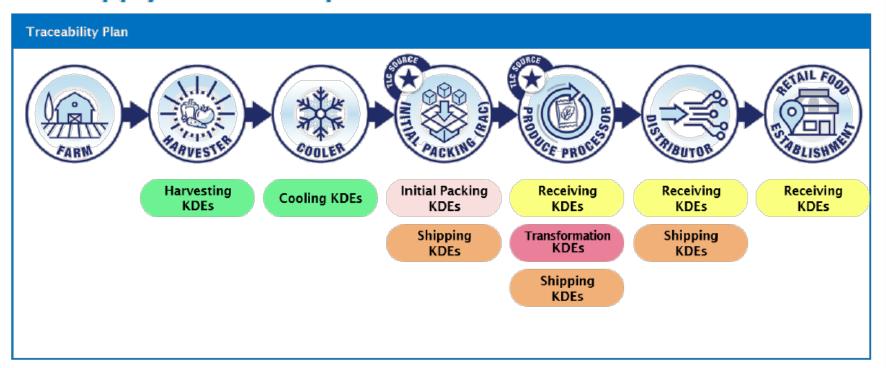| Critical Tracking Events (CTE)	Key Data Elements (KDE)
• Initial packing	– Traceability lot code assigned – Product description as packed – KDEs from Harvest CTE – KDEs from any Cooling CTE – Reference document # – Date packed – Amount packed – Location description of initial packing

• Shipping
• Receiving
• Transform-ation
	– Traceability Lot Code
	– KDEs for the current CTE
	– Next receiver information
	– KDEs from prior CTEs
	  • Harvest, Cool (if done), Pack
	  • Prior Shipping, Receiving, Transformation

SUPPLEMENTAL MATERIAL

Example Scenario from FDA

FDA

Supply Chain Example: Cucumbers

Traceability Plan

FARM → HARVESTER → COOLER → INITIAL PACKING (RAC) (TLC SOURCE ★) → PRODUCE PROCESSOR (TLC SOURCE ★) → DISTRIBUTOR → RETAIL FOOD ESTABLISHMENT

	Harvesting KDEs	Cooling KDEs	Initial Packing KDEs	Receiving KDEs	Receiving KDEs	Receiving KDEs
			Shipping KDEs	Transformation KDEs	Shipping KDEs	
				Shipping KDEs		

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FDA Scenario with PSA Notes

FDA

Supply Chain Example: Cucumbers

Traceability Plan

FARM	HARVESTER	COOLER	INITIAL PACKING (RAC) TLC SOURCE ★	PRODUCE PROCESSOR TLC SOURCE ★	DISTRIBUTOR	RETAIL FOOD ESTABLISHMENT
	Harvesting KDEs	Cooling KDEs	Initial Packing KDEs	Receiving KDEs	Receiving KDEs	Receiving KDEs
			Shipping KDEs	Transformation KDEs	Shipping KDEs	
				Shipping KDEs		

------------------------------ Critical Tracking Events ------------------------------

PSA Notes

Steps by a farm, or a combination of business types				Processor KDEs	Distributor KDEs	Retail KDEs
Growing info • Field ID • Field map • Field GPS	**Harvest KDEs** • Growing info • Commodity • Amount • Etc	**Cooling KDEs** • Location • Date/time • Etc	**Packing KDEs** • Traceability Lot Code (TLC) • All prior KDEs • Etc	• Traceability Lot Code • All prior KDEs • Recipient info • Etc	• Traceability Lot Code • All prior KDEs • Recipient info • Etc	• Traceability Lot Code • All prior KDEs • Source info • Etc

SUPPLEMENTAL MATERIAL

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Additional Resources

- Questions? Ask the FCIC Inquiry Form: https://cfsan.secure.force.com/Inquirypage/

- FDA Final Traceability Rule: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods

- FDA Food Traceability List: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list#List

- FDA Exemptions and Exclusions tool: https://collaboration.fda.gov/tefcv13

- New York State (NYSDAM) Guidance for Produce Traceability: https://agriculture.ny.gov/system/files/documents/2022/04/guidanceforproducetraceability-blueribbon.pdf

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Discussion: Input on the Supplemental Slides

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Traceability Resources

- Interested in more discussion of produce traceability?
  - See the November 2021 Educators' Call: "Produce Traceability: One State's Approach to Improving Traceability Across the Produce Supply Chain"

- Module 7 suggestions about defining a lot and creating a lot code are a resource for farms
  - May or may not be formal Traceability Lot Code

- Industry standard process for traceability, including lot codes, are in development

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Next Educators' Call

- Subpart E (Agricultural Water): Harvest and Postharvest Requirements

  – Date: January 2023 (exact date TBD)

- PSA is working toward an Educators' Call series on postharvest water to highlight outreach efforts and updated/new supporting resources

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PSA Advanced Trainer Workshop

Register Now

PSA Advanced Trainer Workshop

February 7-9, 2023
Lake Alfred, Florida

Are you a PSA Trainer and interested in attending? Register here
https://advancedpsa020723.eventbrite.com

Questions?
Contact Donna Clements
(dmp274@cornell.edu)

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SC Southern Center
for Training, Education, Extension, Outreach, and
Technical Assistance to Enhance Produce Safety

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Now Hiring!

- Interested in joining a motivated produce safety team?

- PSA Spanish-language Extension Associate
  - For position description, visit: https://academicjobsonline.org/ajo/jobs/23900
  - First review will begin January 9th and continue until suitable candidate is identified

- Please encourage anyone who may be interested and qualified to apply!
  - Happy to meet with them to discuss position

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The PSA (Migrated) Website

English: producesafetyalliance.cornell.edu
Spanish: es.producesafetyalliance.cornell.edu