

FDA'S FOOD TRACEABILITY RULE

FSMA SECTION 204

Produce affected
Who & What is exempt?
Requirements for produce farms



Disclaimer

This presentation is a quick overview of the requirements for produce farms and packing houses.

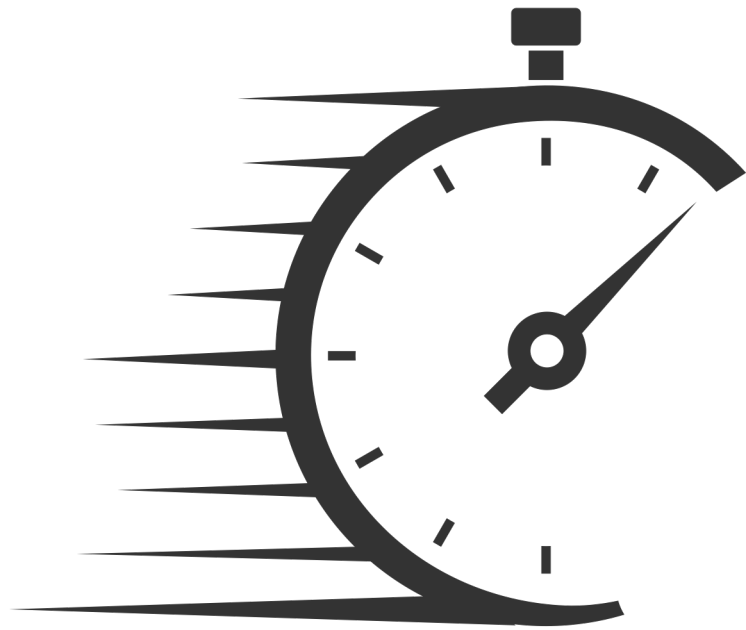
We will not discuss the requirements and exemptions for other foods that are covered by FSMA Food Traceability rule or the requirements for those who further process, restaurants and retail food establishments.

FSMA FOOD TRACEABILITY RULE

SECTION 204

Effective Jan. 20, 2026

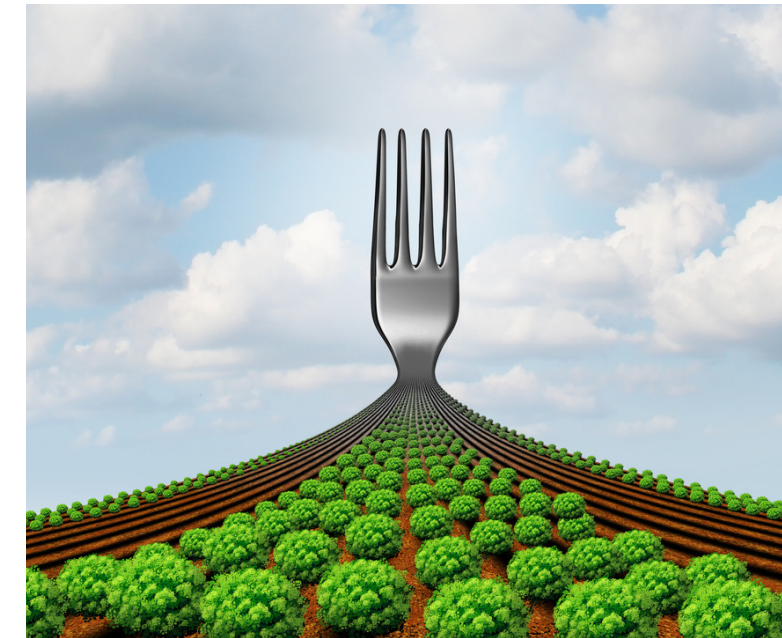
Inspections expected in 2027



**GOAL: FOR FDA TO
RAPIDLY IDENTIFY
THE RECIPIENT OF
FOODS/ PRODUCE
THAT IS INVOLVED
IN OUTBREAKS**



**ONLY FOCUSES ON
FOOD/ PRODUCE IN
THE FOOD
TRACEABILITY LIST**



**RECORDKEEPING &
TRACKING SYSTEM**

**AFFECTS FARMS,
PACKERS,
PROCESSORS
RESTAURANTS,
RETAIL**



**UNINTENDED
CONSEQUENCES:
BUYERS ARE
CONSIDERING
ADOPTING THESE
REQUIREMENTS FOR
ALL COMMODITIES**

Contains Nonbinding Recommendations

**Requirements for Additional
Traceability Records for Certain
Foods:
What You Need to Know About
the FDA Regulation:
Guidance for Industry

Small Entity Compliance Guide**

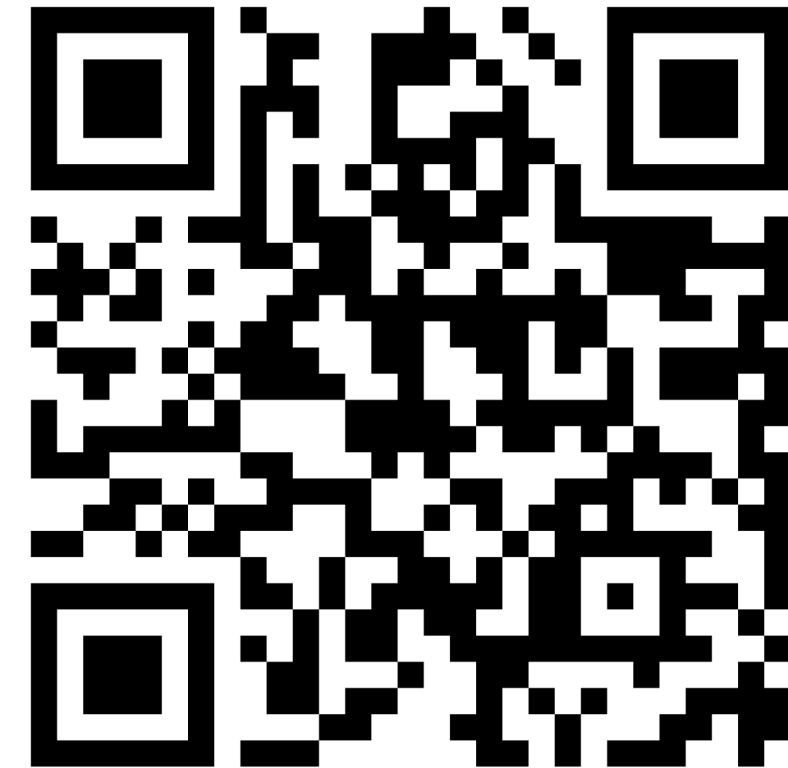
*Additional copies are available from:
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740*

<http://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry>

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-1336.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Analytics and Outreach**

May 2023



TRACEABILITY IN PRODUCE FARMS



UNDER FOOD TRACEABILITY RULE

Traceability plan

Collect records during harvest and cooling

Lot code generated when produce is first packed, stays with the produce until final sale

Lot code & other data is shared & also kept on file

Sortable spreadsheet

FARMS THAT ARE GAP CERTIFIED

Develop a lot code

One step trace back and trace forward

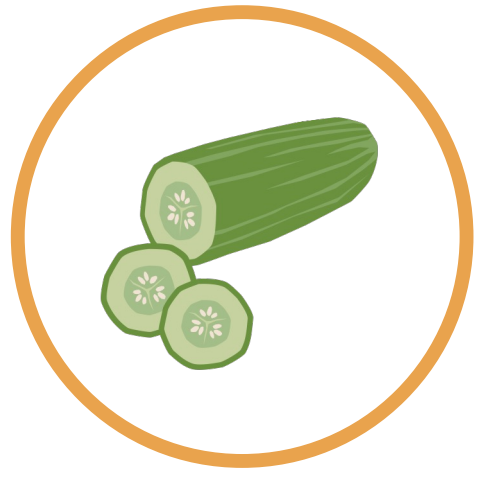
Recall program-
mock recall

Lot code shared

FARM WITH NO BUYER REQUIREMENTS

Usually no practices are implemented for traceability

FOOD TRACEABILITY LIST (PRODUCE)



CUCUMBERS



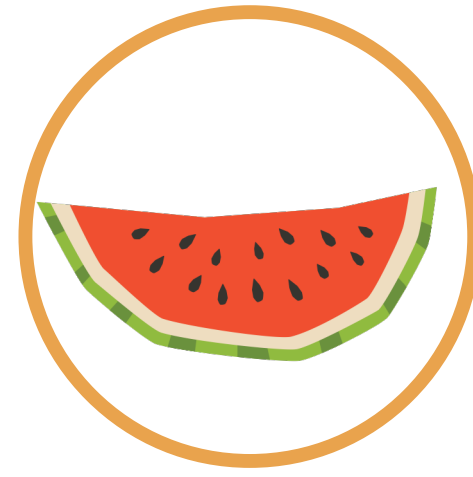
HERBS



**LEAFY
GREENS**



**LEAFY
GREENS
(FRESH CUT)**



**MELONS
(FRESH)**



**FRESH
PEPPERS
(ALL TYPES)**



TOMATOES



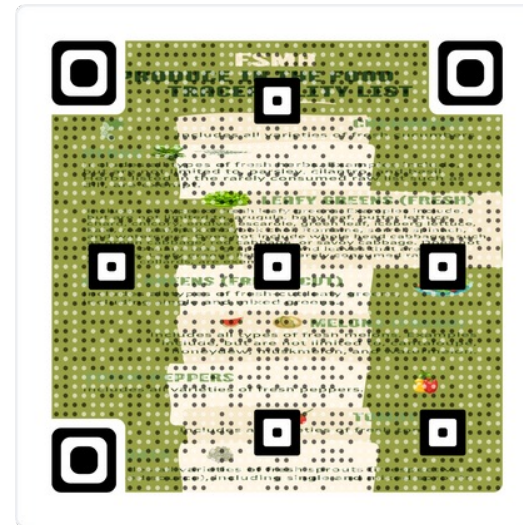
SPROUTS



**TROPICAL
TREE FRUITS**



**FRUITS AND
VEGETABLES
(FRESH CUT)**



Berries are not in the FTL

WHO & WHAT IS EXEMPT (PRODUCE)?



**PRODUCE
USED FOR
PERSONAL
CONSUMPTION**



**FARMS THAT
SELL LESS
THAN \$25,000
IN PRODUCE**

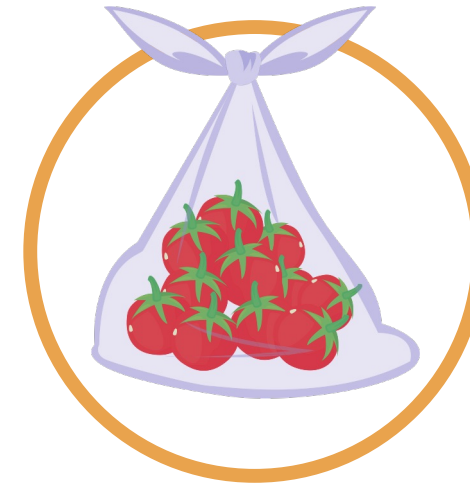
**(LAST 3 YRS)
adjusted for
inflation**

+

**Produce not
covered in
Produce
safety rule**



**PRODUCE
THAT IS SOLD
OR DONATED
DIRECTLY TO
CONSUMERS**



**PACKAGED
PRODUCE**

**PACKAGING
REMAINS IN
PLACE UNTIL IT
REACHES THE
CONSUMER
AND IT IS
PROPERLY
LABELED**



**PRODUCE
THAT
RECEIVES
COMMERCIAL
PROCESSING
WITH A KILL
STEP**

PARTIAL EXEMPTIONS (PRODUCE)



**NON PROFIT FOOD
ESTABLISHMENTS**



**FARM TO
SCHOOL
PROGRAMS**



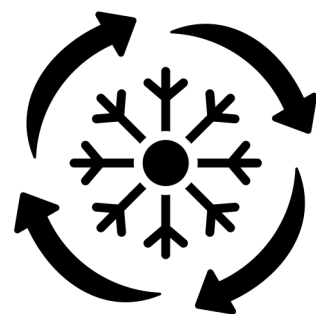
**FOOD FOR
RESEARCH OR
EVALUATION**

ACTIVITIES UNDER WHICH SOME RECORDS ARE GENERATED

1
Harvesting



**When cooling
before initial
packing**



2

3



Initial packer

**LOT CODE IS
ASSIGNED +
RECORDS ARE
COMPILED**

4

Shipping



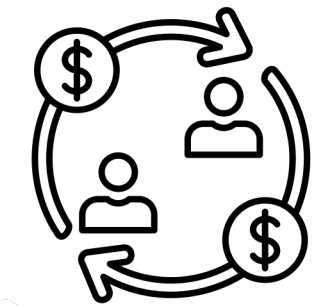
**SEND RECORDS
TO WHO YOU ARE DOING
THE TRANSACTION WITH**

5

Receiving



**WHOEVER RECEIVES
THE RECORDS MUST
KEEP THEM ON FILE
FOR 2 YEARS**



1. Food traceability Plan

Farms & Packinghouses (Update annually)

1. Procedures you use to maintain the records you are required to keep, including the format and location of these records.

2. Identify foods on the Food Traceability List that you manufacture, process, pack, or hold

3. Describe how you assign traceability lot codes to foods on the FTL

4. Point of contact for questions regarding your traceability plan and records

5. A farm map showing the areas in which you grow produce in the FTL List.

The farm map must show 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.

2. Records that need to be collected at harvest and when cooling produce before packing

1	Location description (field or growing area name)	Mt Pisgah Farm #1
2	Commodity/ variety (if applicable)	Tomatoes, Roma
3	Quantity and unit of measure of produce	60 boxes
4	Harvest location	Farm #1
5	Harvest date	8/10/2023
6	Reference document type and reference number	Harvest log 0810

3. Records kept by the Initial Packer



**Collected during
harvest**

- (1) The commodity and, if applicable, variety of produce received;**
- (2) The date produce was received;**
- (3) The quantity and unit of measure of the produce received (e.g., 75 bins, 200 pounds);**
- (4) The location description for the farm where the food was harvested;**
- (5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;**

3. Records kept by the Initial Packer (Cont.)

- (6) Business name and phone number for the harvester of the food;**
- (7) Harvest date**
- (8) The location description for where produce was cooled (if applicable);**
- (9) The date of cooling (if applicable);**
- (10) The traceability lot code assigned;**
- (11) The product description of the packed produce;**
- (12) The quantity and unit of measure of the packed produce (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);**
- (13) The location of the packing house where produce was packed (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;**
- (14) Date of initial packing; and**
- (15) The reference document type and reference document number.**

4. Records shared by the Initial Packer when produce is shipped

(1) The traceability lot code

(2) The quantity and unit of measure (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)

(3) The product description

(4) The location description for where produce is being shipped to

(5) The location where produce is being shipped from

(6) The date you shipped the produce

(7) Traceability lot code source, or the traceability lot code source reference (location where lot code was assigned)

(8) The reference document type and reference document number.

THE **FDA** CALLS THESE ACTIVITIES **CRITICAL TRACKING EVENTS (CTE'S)**

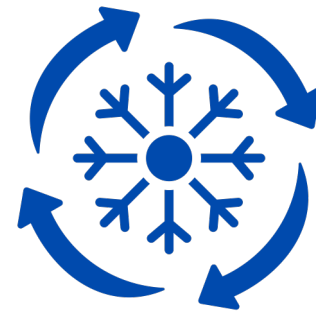
1

HARVESTING



2

**COOLING
BEFORE INITIAL
PACKING**



3

**INITIAL
PACKING**



4

SHIPPING



5

RECEIVING



6

TRANSFORMATION- resulting in a food in the Food traceability list
Manufacturing/processing OR Commingling, repacking, relabeling OR Changing its packing or packaging

FDA calls the records collected for each **Critical Tracking Event (CTE)**, **Key Data Elements (KDEs)**

Example

Records shared by the initial packer when produce is **shipped**

- (1) The traceability lot code for the food;
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 200 pounds);
- (3) The product description for the food;
- (4) The location description for where produce is being shipped to
- (5) The location where produce is being shipped from ;
- (6) The date you shipped the produce
- (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
- (8) The reference document type and reference document number.

6. Electronic sortable spreadsheet

An electronic sortable spreadsheet containing relevant traceability information must be provided to the FDA within 24 hours of a request to assist the FDA during an outbreak, recall, or other threat to public health.

For templates of electronic sortable spreadsheets, scan QR code.

THE PRODUCE
TRACEABILITY
INITIATIVE

CPMA
CANADIAN PRODUCE
MARKETING ASSOCIATION

INTERNATIONAL
FRESH
PRODUCE
ASSOCIATION™



Is your buyer(s) planning to implement FSMA Traceability 204 despite the fact berries are not included in the FTL?

If so, how are they expect the records listed to be provided?

Are they requiring the use of a specific software?

What is the most cost and time efficient way to comply with this regulation or possible buyer requirement?

Thanks for your attention!