

# FSMA PROPOSED TRACEABILITY RULE: WHAT GROWERS NEED TO KNOW

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# Goals for Today

Provide	Provide background on the history of the Rule and Scope
Identify	Identify what produce will be subject to the Rule
Show	Show how the proposed rule is designed to “work”
Explain	Explain recordkeeping requirements
Recognize	Recognize limited exemptions
Discuss	Discuss the CFVGA food safety committee’s plans for developing and submitting comments
Ask	Ask for your feedback on the rule & to sign up one- on-one with a food safety committee member so that we can draft effective Association comments

# History of the Proposed Rule & Scope

- Last Mandatory rule from the Food Safety Modernization Act, signed Jan 4, 2011
- Section 204 of FSMA
  - Required FDA to commission a series of pilot projects
  - Requires the designation of certain high-risk foods, based upon foodborne illness outbreak data from CDC
  - Requires that the FDA establish certain additional recordkeeping requirements
    - Must be technology neutral
    - Science-based
    - Scale-appropriate
- Originally list was required to be proposed within 1 year, Proposed Rule within 2 years
- Center for Food Safety sued for failing to issue this rule, produced on a court ordered deadline in September 2020
- Broadest FSMA rule – includes PERSONS, not just farms and facilities
  - Distributors, Restaurants, and Retailers will be required to keep records
- Comments are currently due February 22, 2021

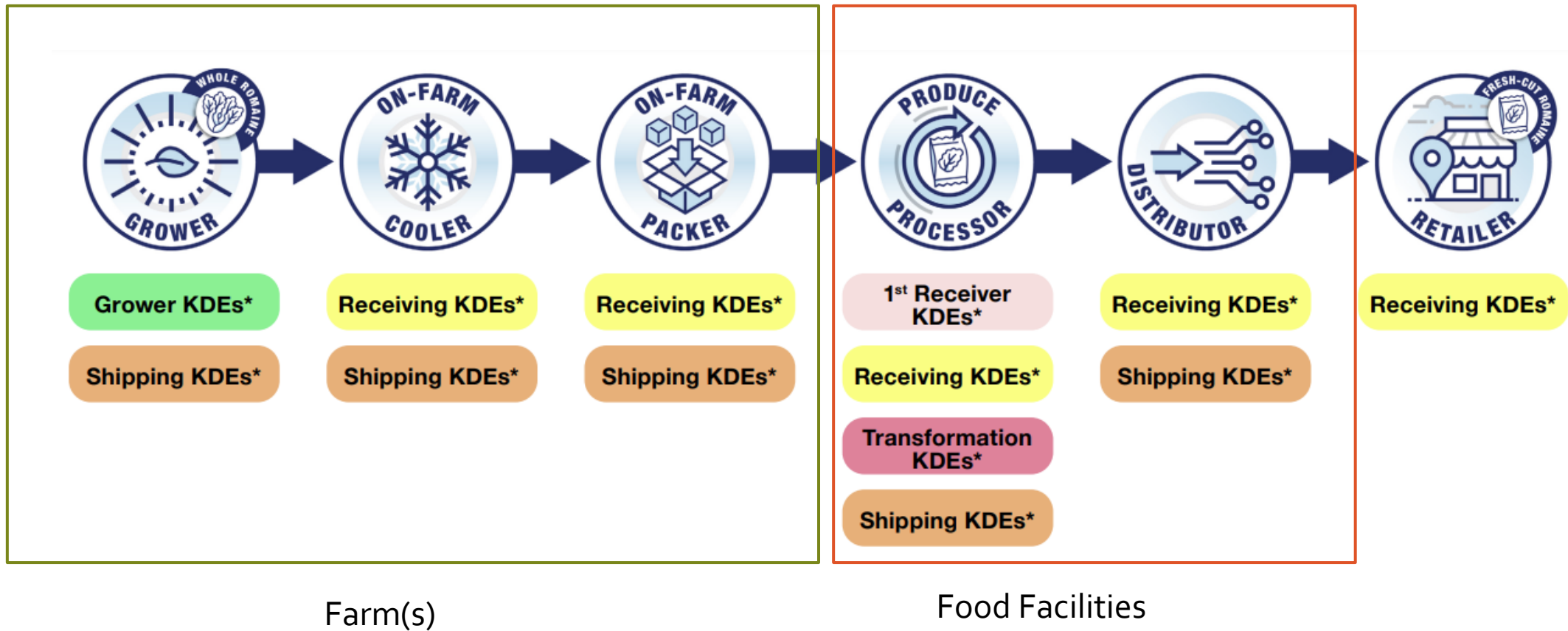
# Establishes The Food Traceability List

- Contains certain produce
  - i. Cucumbers
  - ii. Fresh herbs
  - iii. Leafy greens (including fresh cut)
  - iv. Melons -- (including watermelons)
  - v. Peppers
  - vi. Sprouts
  - vii. Tomatoes
  - viii. Tropical tree fruits
  - ix. ALL Fresh cut fruits and veggies (unless not customarily consumed raw)

# Defines Key Data Elements (KDEs) to be collected during ALL Critical Tracking Events (CTEs)

- The Critical Tracking Events
  - GROWING
  - RECEIVING
  - CREATING
  - TRANSFORMING
  - SHIPPING
- Most growers of produce on the FTL will be doing (if regulated as a farm)
  - GROWING
  - SHIPPING
  - And may be RECEIVING
- And may be (especially if you are a registered food facility)
  - GROWING, RECEIVING, CREATING, TRANSFORMING, SHIPPING -- *see bonus slides*

# How this “works” – FDA Example #1



# Core Concepts/Definitions

- **Farm:** same (problematic) definition we have from the PSR
  - **First-Receiver:** first non-farm entity to receive produce listed on the FTL
  - **Traceability product description:** commercial description of the product used for stocking or selling, including the category code or term, and trade description (**assigned by the entity**)
  - **Traceability product identifier:** unique identification code (often alphanumeric) that an entity assigns to specific type of product (**assigned by the entity**)
  - **Traceability lot code:** descriptor (often alphanumeric) assigned to a particular lot (**CANNOT be changed until transformation – will be generated by the Farm or First Receiver**)
  - **Location Description:** A complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code
  - **Location Identifier:** A unique identification code that an entity assigns to the physical location name identified in the corresponding location description
  - **POC:** Point of contact – name of the responsible individual
- See the FDA Glossary <https://www.fda.gov/media/143468/download>



# Farm Growing KDE requirements

CTE Definition or Example	Required KDEs to be collected/generated
You grow one or more types of produce on the FTL	- Traceability lot code linked to growing area coordinates for each grown FTL food

# Farm Shipping KDE requirements

CTE Definition or Example	Required KDEs to be collected/generated
You sell or ship one or more types of produce on the FTL from your farm	<ul style="list-style-type: none"><li>- Statement that you are farm under the FDA definition of “farm”</li><li>- Location identifier and location description of the originator of the food</li><li>- Business name, POC, and phone number of the <b>harvester</b> of the food (if not the shipper) and the <b>DATE</b> and <b>TIME</b> of <b><u>harvesting</u></b></li><li>- Location identifier and location description of the place where the food was cooled (if not by the shipper) and the <b>DATE</b> and <b>TIME</b> of <b><u>cooling</u></b></li><li>- Location identifier and location description of the place where the food was packed (if not by the shipper) and the <b>DATE</b> and <b>TIME</b> of <b><u>packing</u></b></li></ul>

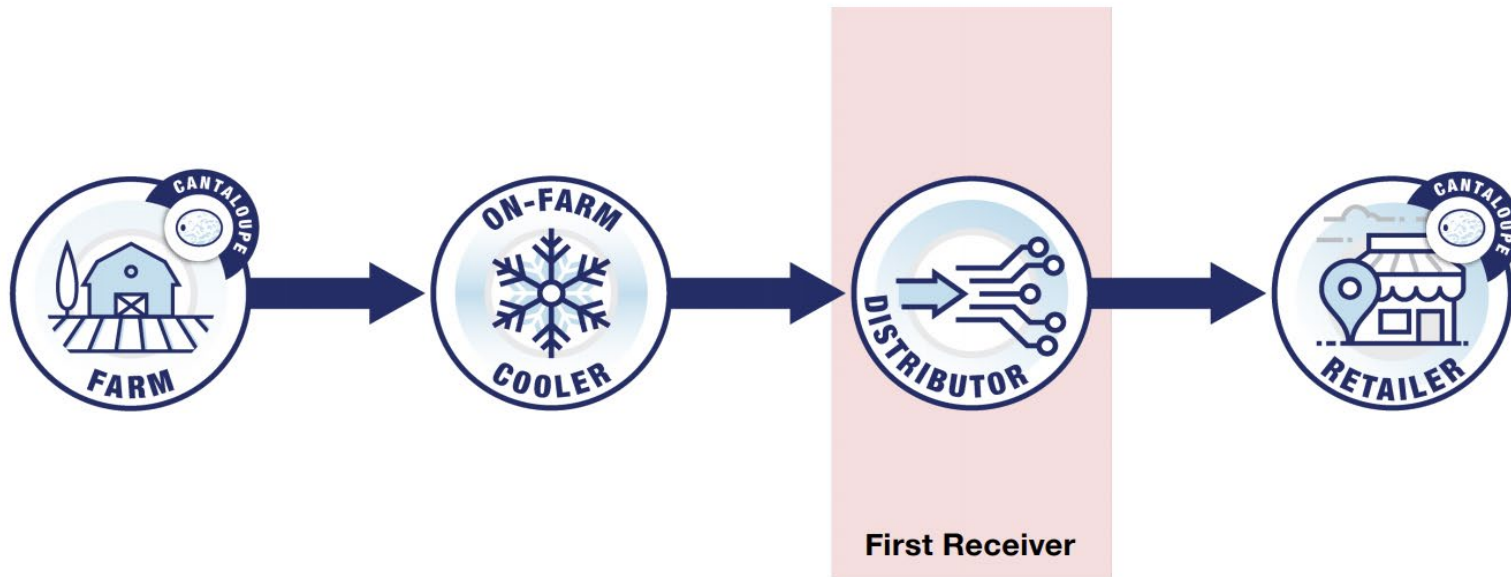
As written, a farm or the first receiver may assign the **traceability lot code** linked to all of the Farm Shipper information

# Farm Receiving KDEs

CTE Definition or Example	Key Data Elements that must be collected
<p>Receiving (ALL persons receiving a listed food <i>other than consumers</i>)</p> <p>EX:</p> <ul style="list-style-type: none"><li>--you receive listed produce for another farm to pack or cool and meet the definition of a "primary production farm" or a "secondary activities farm"</li><li>--packers</li><li>--aggregators</li><li>--distributors</li></ul>	<ul style="list-style-type: none"><li>-<b>ALL receivers</b></li><li>-Location identifier &amp; location description for immediate previous source</li><li>-Entry number (if an imported food)</li><li>-Location identifier &amp; location description for where food received + date &amp; time of receipt</li><li>-Quantity &amp; unit of measure of the food</li><li>-Traceability product identifier</li><li>-Location identifier &amp; location description for the lot code generator</li><li>-Reference record types and numbers where information is stored</li><li>-Name of the transporter</li></ul>

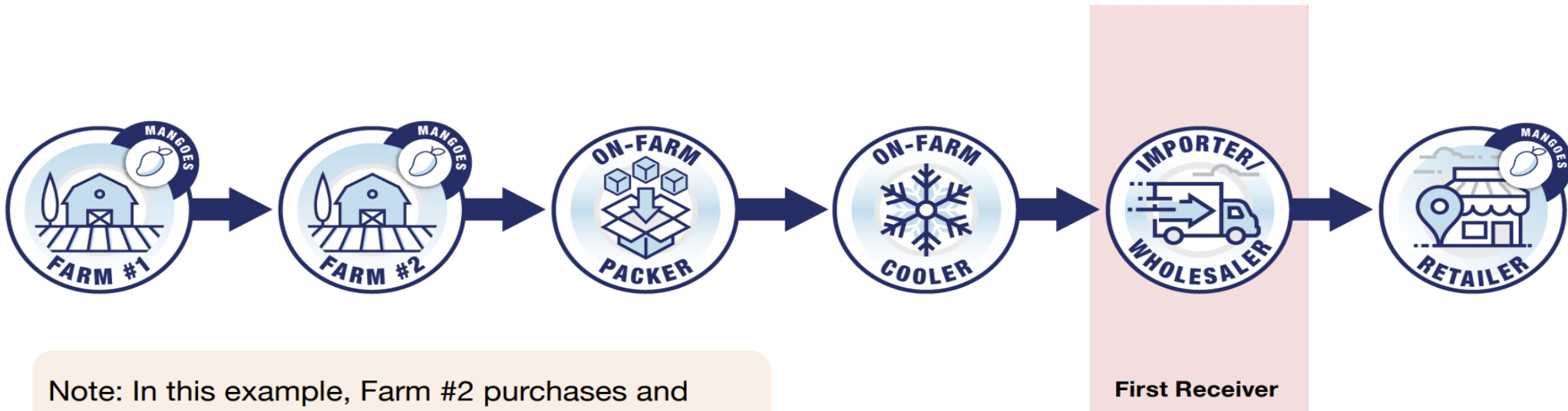
# FDA Example #2

## Cantaloupe



# FDA Example #3

## Mangoes



Note: In this example, Farm #2 purchases and takes physical possession of the mangoes from Farm #1. However the Importer/Wholesaler would be considered the First Receiver, since that is the first non-farm entity who receives the food.

# Requires Additional Traceability Records

- Description of the reference records
- List of all FTL food shipped
  - For diversified growers, this is a detailed classification exercise
- Description of how traceability lot codes are assigned
- Supplemental information necessary to understand the firm's traceability system

# Adds Record Retention, Form, and Availability Requirements

- a. Must be available within 24 hours of a record request
- b. Maintained for 2 years
- c. And, **be made available in an electronic and sortable spreadsheet within 24 hours of FDA request**

# Gives Limited Farm Exemptions

- **Exemptions for Listed Foods that receive certain types of processing -- “kill step”**
  - Follows the commercial processing exemption of the produce safety rule
    - Canning, cooking, juicing, pasteurization, etc.
- **Requirements for foods later subject to a kill step**
  - Records not required for subsequent shipping, but records are required for
    - Receiving listed food
    - Application of the kill step to the listed food
- **Farms with less than \$25,000 in produce under the PSR calculation**
- **Farm direct sales to consumers**
  - **(NO PARALELL QUALIFIED EXEMPTION TO THE PSR)**



# Additional Limited Farm Exemptions

- **Food produced and packaged on a farm in fully enclosed container that maintains the integrity of the product to prevent subsequent contamination or alteration of the product & reaches the consumer with the full name, complete address, and phone number of where the product was packed**
  - Clamshells with holes, cardboard boxes, plastic bags with holes, netted bags are NOT eligible for this exemption
- **Produce that is rarely consumed raw**
- **Partial exemption for farm to school or farm to institution sales** – the school food authority or entity is only required to document the name and address of the farm for 180 days.

# Creates Limited Exemptions for other parts of the Supply Chain

- **Transporters**
- **Co-Proposal for Small Retail Food Establishments (RFEs)**
  - i. Full exemption: RFEs that employ 10 or fewer full-time employees (FTEs) OR
  - ii. Partial exemption: RFEs that employ 10 fewer FTEs would only be exempt from the 24-hour spreadsheet requirement

# Offers a Limited Waiver Process

- **Only granted for a showing of “economic hardship”**
  - Economic hardship might be unique operations or geography
    - Not low revenue or few employees
  - For a “type” of entity – citizen petition
  - Individual entity – Written request for waiver
- **Waivers can be revoked**

# Sets Compliance Dates

- Effective Date – 60 days after final publication
- Compliance date – 2 years after Effective Date
- **In English** – 2 years and 60 days after FDA publishes the final rule

# CFVGA Food Safety Committee Concerns

- **Problems with relying on the existing farm definition when it is under revision**
  - **Gets very complicated with smaller growers and packhouses to know what their actual responsibility will be**
    - **Is the farm generating the lot code?**
    - **The pack house?**
    - **Or is the pack house a first receiver?**
- **No similar exemption as under the PSR for qualified exempt growers**
- **Education by whom, how, when, and with what resources?**
  - **Challenges of educating growers – no minimum or continuing education requirement, high variability of traceability systems**
- **Too short a timeline for compliance**

# CFVGA Food Safety Concerns

- **Enforcement by whom, how, and when?**
  - Farms – will Departments of Agriculture be allowed to inspect for this? FDA, or is this just in the event of a foodborne illness outbreak? Retailers outside of FDA jurisdiction?
- **Requires very detailed collection of data not currently recorded in many farm traceability programs**
  - **Date, time, location of harvest, cooling, and packing --- more commonly date and field, but not time specific data**
    - Harvest and cooling intervals may span a significant period of time
    - Practically, how does that get recorded?
- **Confidentiality concerns: Sharing of very farm specific data with the entire supply chain – why not just to FDA?**
- **Variation in record keeping systems – paper based to electronic – a sortable spreadsheet within 24 hours could be a lot.**

# What You Can Do

1. **Learn more about the Proposed Food Traceability Rule here:**
  - <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability>
  
2. **Sign up to give feedback to the CFVGA Food Safety Committee so we can draft comments**
  - FDA has asked for feedback about specific supply chains and how the rule does/does not appropriately map onto those supply chains
  - Ask you to sign up to meet one-on-one with a food safety committee member
    - We'll have specific questions, and ask you to share your concerns
    - Will anonymize for sharing with the agency.
  - Sign up here:  
[http://colostate.az1.qualtrics.com/jfe/form/SV\\_ey5ijZ3RN8QhaOV](http://colostate.az1.qualtrics.com/jfe/form/SV_ey5ijZ3RN8QhaOV)
  
3. **Take the Western Growers Survey to include in the WGA comments**
  - Marilyn will circulate once the survey is developed
  
3. **Submit your individual comments using a Grower Form Letter drafted by the CFVGA Food Safety Committee**
  - Include the concerns from the prior slide & general feedback from one-on-one meetings
  - You add operation specific concerns (what you produce that will be impacted, your specific concerns)
  - Submit here before February 22, 2021 (unless this deadline is extended)

<https://www.regulations.gov/comment?D=FDA-2014-N-0053-0056>



# QUESTIONS?

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Please type into the Q&A box

Feel free to direct to me or any CFVGA Committee Member – We can all weigh in





**BONUS SLIDES FOR FDA  
REGISTERED FOOD FACILITIES**

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# Food Facility CTEs – Receiving

Receiving definition/example	Key Data Elements
<p>Receiving (ALL persons receiving a listed food <i>other than consumers</i>)</p> <p>EX: --you are a registered food facility and you receive products from another farm</p>	<ul style="list-style-type: none"><li>-<b>ALL receivers</b></li><li>-Location identifier &amp; location description for immediate previous source</li><li>-Entry number (if an imported food)</li><li>-Location identifier &amp; location description for where food received + date &amp; time of receipt</li><li>-Quantity &amp; unit of measure of the food</li><li>-Traceability product identifier</li><li>-Location identifier &amp; location description for the lot code generator</li><li>-Reference record types and numbers where information is stored</li><li>-Name of the transporter</li> <li>-<b>ADDITIONAL requirements for “first receivers”</b></li><li>- first non-farm entity to receive a listed food after grown/raised/harvested/caught</li><li>-Location identifier &amp; location description of originator</li><li>-Business name, POC, phone of the harvester</li><li>-Location identifier &amp; location description of cooling, date and time of cooling (if applicable)</li><li>-Location identifier &amp; location description of packing, date and time of packing (if applicable)</li></ul>

# Food Facility CTEs – Creation

Creation definition/example	Key Data Elements
<p>You create a listed food from non-listed foods</p> <p>Example: You chop onions, creating fresh cut onions</p> <p>Onions are not FTL produce, but ALL fresh cut produce is a listed food</p>	<ul style="list-style-type: none"><li>-Location identifier &amp; location description where transformation occurs AND date creation completed</li><li>-traceability product identifier and traceability lot code of the created listed food</li><li>-Quantity and unit of measure of listed food produced</li></ul> <p>Reference record types and numbers where information is stored</p>

# Food Facility CTEs – Transformation

Transformation Definition/Examples	Key Data Elements
<p>You create a new listed food from another listed food</p> <p>Example: You chop leafy greens to make a salad mix</p> <p>Leafy greens are listed produce, and all fresh cut produce is a listed food</p>	<ul style="list-style-type: none"><li>-Location identifier &amp; location description where transformation occurs AND date creation completed</li><li>-traceability product identifier and traceability lot code of the created listed food</li><li>-Quantity and unit of measure of listed food produced</li></ul> <p>Reference record types and numbers where information is stored</p>

# Food Facility CTEs – Shipping

Shipping Definition/Examples	Key Data Elements
<p>You ship listed produce, transformed FTL produce, or a created FTL food (like chopped onions) <u>from your FDA registered food facility</u></p> <p>EX:</p> <ul style="list-style-type: none"><li>--you are a registered food facility, and you ship your products (and probably others' products)</li><li>--ship to a distributor</li></ul>	<ul style="list-style-type: none"><li>-Entry number (if an imported food) for listed food</li><li>-Quantity and unit of measure of listed food shipped</li><li>-Traceability product identifier &amp; traceability product description of food</li><li>-Location identifier &amp; location description for the lot code generator</li><li>-Location identifier &amp; location description for immediate recipient</li><li>-Location identifier &amp; location description for person from which food was shipped</li><li>-Reference record type(s) and record numbers</li></ul>