

# Proposed Rule: Requirements for Additional Traceability Records for Certain Foods Supply Chain Example

### **Andrew Kennedy**

New Era Technology Team Leader, FDA Office of Food Policy and Response



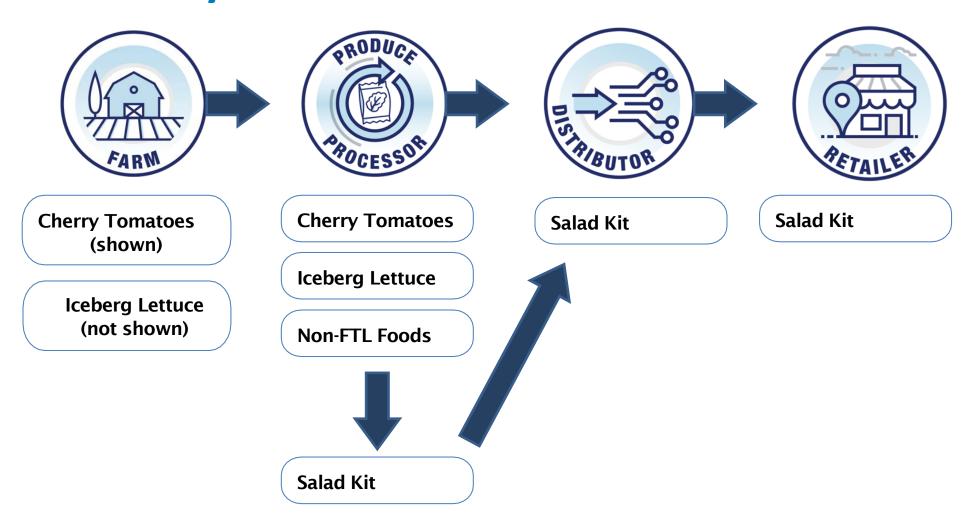
#### **Overview**

- We will walk through a basic example of a salad kit prepared with tomatoes and iceberg lettuce
- The focus will be on the tomato grower, salad kit maker, distributor and retail store.
- This presentation shows abbreviated data due to time constraints
- To see the detailed supply chain records in spreadsheet format, a link will be shared when the presentation is posted online.





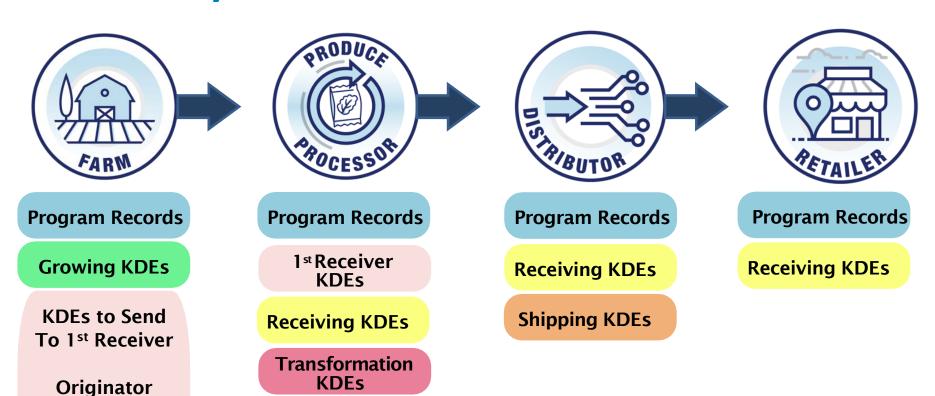
## Example: Salad Kit Supply Chain, cherry tomato farm records will be shown







## Example: Required Records for Salad Kit Supply Chain, cherry tomato farm records will be shown



**Shipping KDEs** 

**Shipping KDEs** 

Harvester

**Cooling Packing** 

### **Scenario Overview**





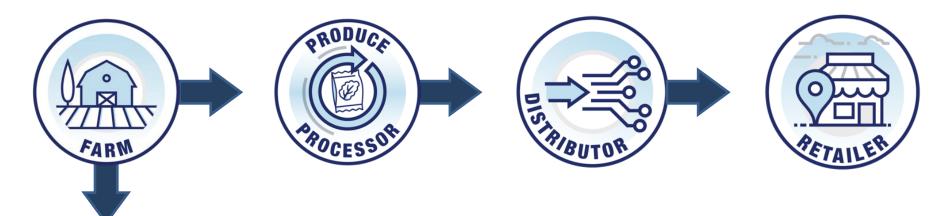
- Tom's Produce is a large produce growing company that contracts with several companies to grow, harvest, pack and ship fresh produce, including cherry tomatoes
- They retain ownership of the crop from planting to shipment to customers.
- The organizations they work with are:
  - Tom's Tomato Farm #1 owned by Tom Jr.
  - Harry's Harvesting harvests the tomatoes
  - Pattie's Packers cools and packs the tomatoes
  - Johnson's Storage stores and ships packed tomatoes for Tom's Produce
- These slides do not focus on the iceberg lettuce in the salad kids, which is sourced from a different company

## Tomato Grower





## Farmer's Traceability Program Records, Description of Reference Records



#### § 1.1315(a)(1) Example of a reference record description (Bill of Lading)\*

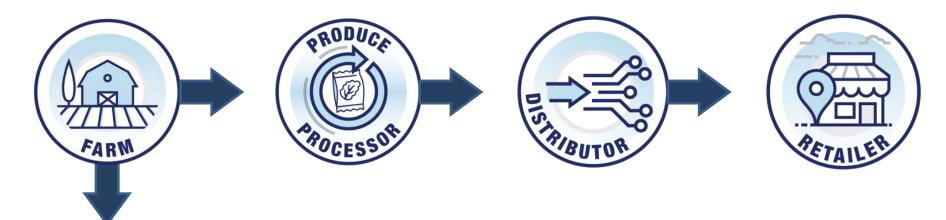
Rule CTE	Reference Record	Rule KDEs	Field Name on Record
Shipping	Bill of Lading	Reference record type and number	Bill of Lading Number (BOL #)
Shipping	Bill of Lading	Import entry number	Not Applicable
Shipping	Bill of Lading	Transporter name	Carrier
Shipping	Bill of Lading	Traceability lot code	Lot
Shipping	Bill of Lading	Quantity and unit of measure	Qty, UOM
Shipping	Bill of Lading	Traceability product identifier	Product ID
Shipping	Bill of Lading	Traceability product description	Product Description

(\*) The BOL is the reference record where Tom's Produce maintains some but not all of the required KDEs. The farm's full traceability program records list the other reference records where other required KDEs are maintained.





### Farmer's Traceability Program Records, Listing of FTL foods shipped by Farmer



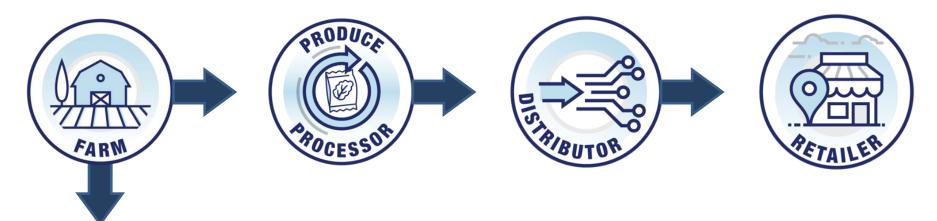
#### § 1.1315(a)(2) List of foods on the Food Traceability List shipped

Traceability Product Identifier	Category Code or Term	Category Name	Brand Name (Trade Description)	Commodity (Trade Description)	Variety (Trade Description)	Product Name (Trade Description)	Packaging Size (Trade Description)	Packaging Style (Trade Description)
614141007349	100061621	Cherry TomatoesRound	Tom's Produce	Tomatoes	Cherry	n/a	10 LB	Case
614141007350	100061621	Cherry TomatoesRound	Tom's Produce	Tomatoes	Cherry	n/a	20 LB	Case





## Farmer's Traceability Program Records, Traceability Lot Code Assignment Method



#### § 1.1315(a)(3) Description of how traceability lot codes are established and assigned

Traceability Lot Code Assignment Method	Traceability Lot Code Format	Example
Lot codes are assigned based on the commodity/ variety, location and harvest date.	COM-VAR-LOC-DDMMYY	TOM-CHE-TTF1-091620 = Tomato - Cherry - Tom's Tomato Farm #1 - Sep 16, 2020





## Farmer's Traceability Program Records, Other Information, Location Master Listing



#### § 1.1315(a)(4) Other Information, Example of Location Master Data Listing

Location Identifier	Business Name (Location Description)	Physical Location Name (Location Description)	Primary Phone (Location Description)	Street Address or Geographical Coordinates (Location Description)	City (Location Description)	State (Location Description)	ZIP Code (Location Description)
TP	Tom's Produce	Tom's Produce HQ	111.111.1111	100 Birch	Tomato City	FL	999999
TTF1	Tom's Produce	Tom's Tomato Farm #1	444.444.4444	26.422831, - 81.420123	Tomato City	FL	999999
PP-PS	Patties' Packers	PP Packing Shed	666.666.6666	260 Birch	Tomato City	FL	999999





### Farmer's Growing KDEs (Kept)



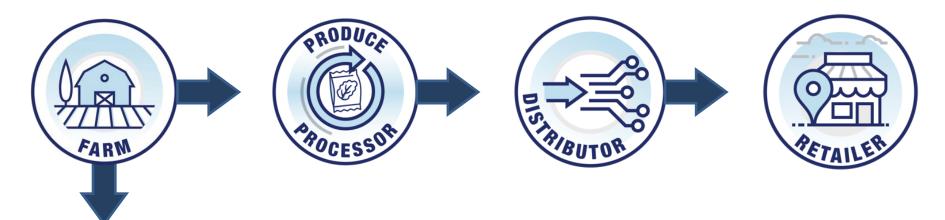
§ 1.1325(a) Records of Growing a Food on the Food Traceability List, Growing Area Coordinates (Kept)

Traceability Lot Code	Growing Area Coordinates
TOM-CHE-TTF1-091620	26.422831, -81.420123
TOM-CHE-TTF1-091820	26.422831, -81.420123
TOM-CHE-TTF1-091920	26.423421, -81.423456





## Farmer's Shipping KDEs, Product Information (Kept and Sent)



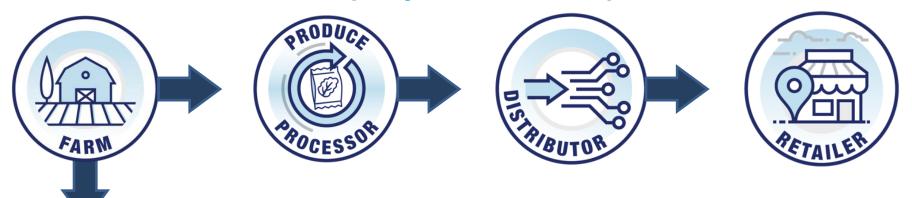
#### §§ 1.1350(a)(2) and (3) Product Information (kept and sent)

Traceability Lot Code	Quantity and Unit of Measure	Traceability Product Identifier	Traceability Product Description(*)
TOM-CHE-TTF1-092120	140 Cases	614141007349	Cherry Tomatoes, 10 LB Case

(\*) Refer to slide, "Farmer's Program Records, Listing of FTL foods shipped by Farmer". The farmer can shorten the product description in individual records because the full traceability product description for each traceability product ID is listed in the farm's traceability program records.



## Farmer's Shipping KDEs, Traceability Lot Code Generator (Kept and Sent)



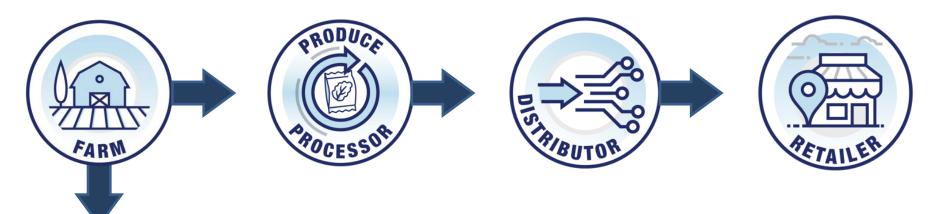
#### § 1.1350(a)(4) Traceability Lot Code Generator (kept and sent)

Location Identifier	Location Description (*)	Point of Contact Name	Phone	Email
ТР	Tom's Produce Headquarters	Tom Orange	444-444-4445	tlcg@tp.com





## Farmer's Shipping KDEs, Ship-To Information (Kept and Sent)



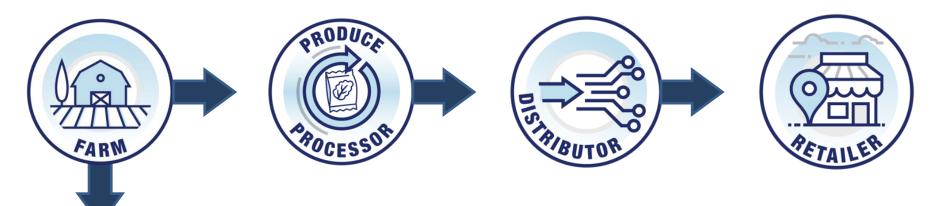
#### § 1.1350(a)(5) Immediate subsequent recipient (kept and sent)

Location Identifier	Location Description(*)
FP-PL-16	Fresh Processor, Plant #16





## Farmer's Shipping KDEs, Ship-From Information (Kept and Sent)



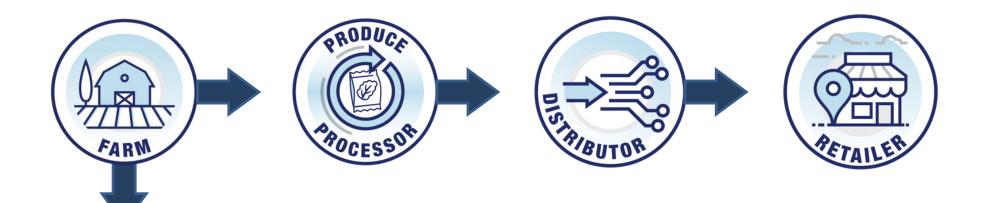
§ 1.1350(a)(6) Location from which the food was shipped, and date and time (kept and sent)

Location Identifier	Location Description(*)	Shipment Date and Time
JS-W4	Johnson Storage Warehouse #4	9/18/20 4:00 AM





### Farmer's Shipping KDEs, Records to be Kept Only



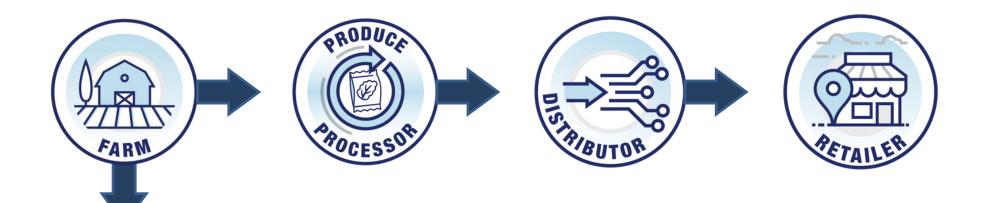
§§ 1.1350(a)(7) and (8) Reference Record, and Transporter (kept only)

Reference Record Type and Number	Transporter Name	
BOL 456789	ABC Shipping Co.	





### Farmer's Send-Only KDEs: Farm Statement



§ 1.1350(b)(2)(i) Statement if the shipper is a farm (sent only).

"Shipper is a farm"





## Farmer's Send-Only KDEs: Originator



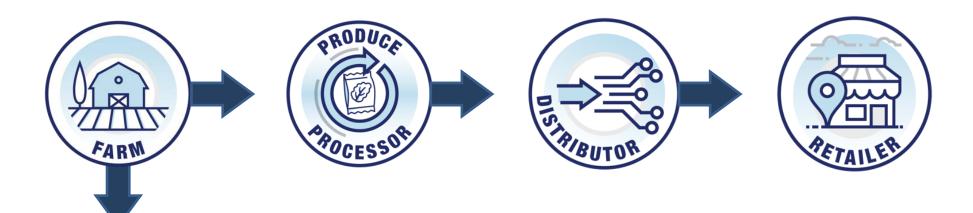
§ 1.1350(b)(2)(ii) the location identifier and location description of the originator of the food (if not the shipper)

Location Identifier	Location Description (*)
TTF1	Tom's Tomato Farm #1





## Farmer's Send-Only KDEs: Harvesting



§ 1.1350(b)(2)(iii) the business name, point of contact, and phone number of the harvester of the food (if not the shipper), and the date(s) and time(s) of harvesting

Business Name	Point of Contact	Phone Number	Harvest Date & Time
Harry's Harvesting	Harry Houdini	555.555.5555	9/16/20 9:00 AM





## Farmer's Send-Only KDEs: Cooling



§ 1.1350(b)(2)(iv) the location identifier and location description of the place where the food was cooled (if not by the shipper), and the date and time of cooling

Location Identifier	Location Description	Cooling Date & Time
PP-PS	Pattie's Packers Packing Shed	9/17/20 10:00 AM





## Farmer's Send-Only KDEs: Packing



§ 1.1350(b)(2)(v) the location identifier and location description of the place where the food was packed (if not by the shipper), and the date and time of packing

Location Identifier	Location Description	Packing Date & Time
PP-PS	Pattie's Packers Packing Shed	9/17/20 3:00 PM

### **Scenario Overview**





• Fresh Processor receives ingredients and processes them to create salad kits.

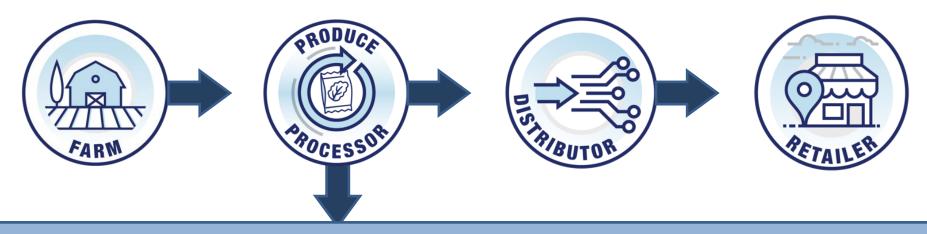
- The organizations they work with are:
  - Tom's Produce cherry tomato source
  - Lizzie's Lettuce leafy green grower (grower KDEs are not shown; lettuce is only shown in transformation step)
  - Food Distributors receives salad kits from Fresh
     Processor and distributes salad kits to Retailer

### Fresh Processor





## **Processor's Traceability Program Records**



#### § 1.1315(a) Traceability Program Records

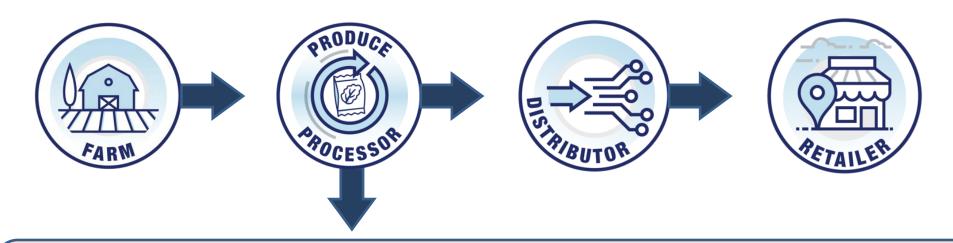
- Description of Reference Records
- Listing of FTL Foods shipped
- Traceability Lot Code Assignment Method
- Other Information, Location Master Listing
- Other Information, Listing of FTL Foods Received

Abbreviated for time, please see Tomato Grower for detailed examples of program records





### **Processor's First Receiver KDEs**



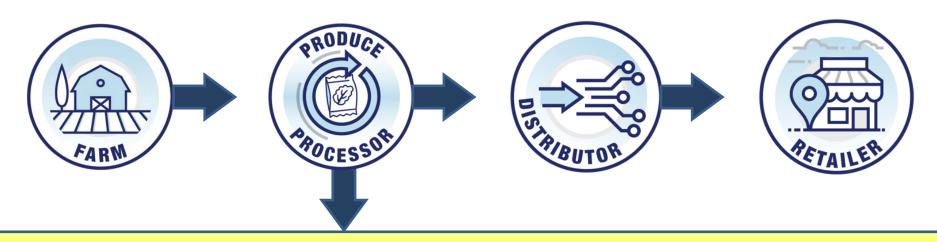
#### § 1.1330 What records must I keep when I am the first receiver of a food on the Food Traceability List

- Originator Location Identifier and Location Description
- Harvester Business Name, Point of Contact, Phone, Harvest Date and Time
- Cooling Location Identifier and Location Description, Cooling Date and Time
- Packing Location Identifier and Location Description, Packing Date and Time
- Linked to Traceability Lot Code





## **Processor's Receiving KDEs**



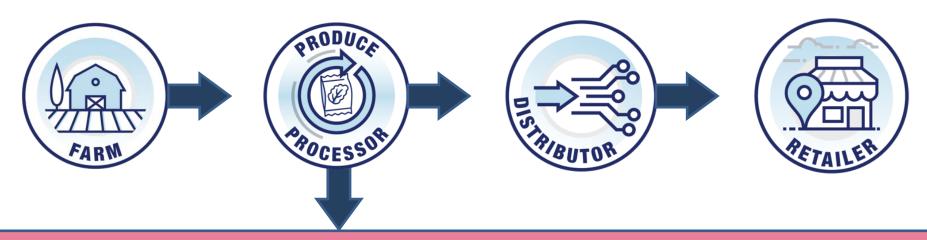
#### § 1.1335 What records must I keep when I receive a food on the Food Traceability List

- Traceability Product ID and Description, Traceability Lot Code, Quantity and UOM
- Source Location ID and Description
- Recipient Location ID and Description, Receipt Date and Time
- Traceability Lot Code Generator Location ID and Description, Point of Contact
- Reference Record Type and Number and Transporter
- Import Entry Number if imported

Abbreviated for time, please see Tomato Grower's Shipping KDEs for detailed examples



## **Processor's Transformation KDEs: Foods Used**



#### § 1.1340(a)(1) Food(s) on the Food Traceability List used in transformation.

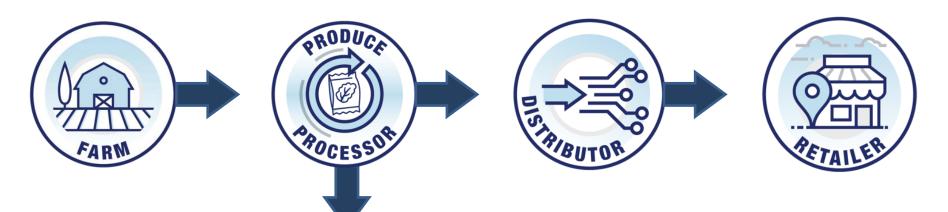
Traceability Lot Code	Quantity	Traceability Product Identifier	Traceability Product Description(*)
TOM-CHE-TTF1-091620	100 Cases	614141007349	Cherry Tomatoes, 10 LB Case
ZZZ-091920	50 Cases	348103223852	Iceberg Lettuce, 20 LB Case

(\*) This processor can shorten the product description in individual records because the full traceability product description for each traceability product ID is listed in the processor's traceability program records.



## Processor's Transformation KDEs: Foods Produced





#### § 1.1340(a)(2) Foods produced through transformation.

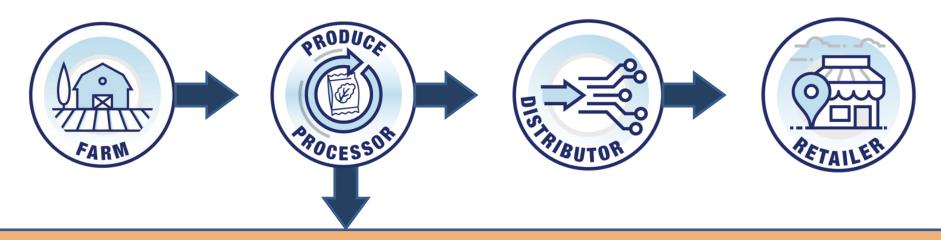
New Traceability Lot Code	Transform Location Identifier	Transform Location Description(*)	Transform Date Completed	Quantity and UOM	Traceability Product Identifier	Traceability Product Description(*)	Reference Record Type and Number
FPP16-091920	FP-PL-16	Fresh Processor, Plant #16	9/19/2020	200 Cases	999999	Garden Salad Kit, 10 X 12 OZ (UPC: 9999999)	WO 123456

(\*) This processor can shorten the product and location descriptions in individual records because the full set of information is listed in the processor's traceability program records. Showing UPC in description is not a requirement, it reflects a common business practice.





## Processor's Shipping KDEs, Product Information (Kept and Sent)



#### §§ 1.1350(a)(2) and (3) Product Information (kept and sent)

Traceability Lot Code	Quantity and Unit of Measure	Traceability Product Identifier	Traceability Product Description(*)
FPP16-091920	200 Cases	999999	Garden Salad Kit, 10 X 12 OZ (UPC: 9999999)

(\*) This processor can shorten the product descriptions in individual records because the full set of information is listed in the processor's traceability program records. Showing UPC in description is not a requirement, it reflects a common business practice.



Processor's Shipping KDEs, Traceability Lot Code Generator (Kept and Sent)



#### § 1.1350(a)(4) Traceability Lot Code Generator (kept and sent)

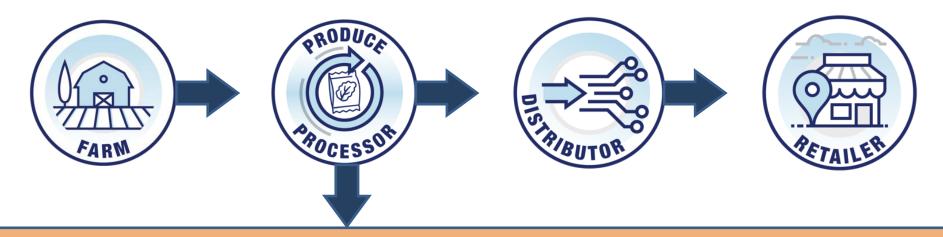
Location Identifier	Location Description (*)	Point of Contact Name	Phone	Email
FP-PL-16	Fresh Processor, Plant #16	Bob Brown	777-777-7778	bbrown@processor.com

(\*) This processor can shorten the location descriptions in individual records because the full set of information is listed in the processor's traceability program records.





## Processor's Shipping KDEs, Ship-To Information (Kept and Sent)



#### § 1.1350(a)(5) Immediate subsequent recipient (kept and sent)

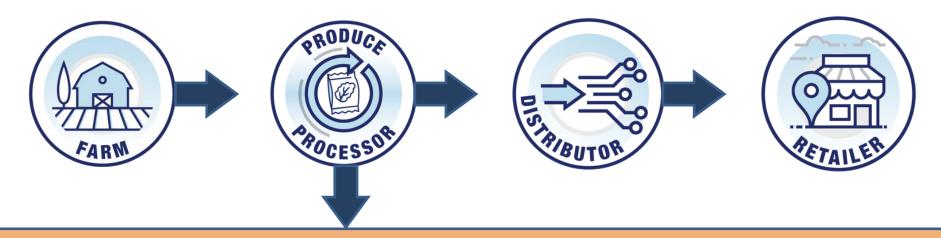
Location Identifier	Location Description(*)
DC-100	Food Distributors, DC #100

(\*) This processor can shorten the location descriptions in individual records because the full set of information is listed in the processor's traceability program records.





## Processor's Shipping KDEs, Ship-From Information (Kept and Sent)



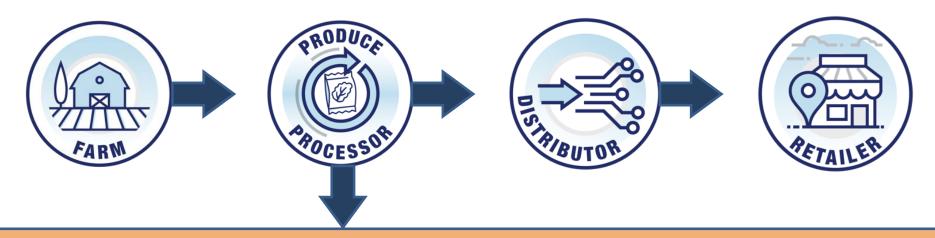
§ 1.1350(a)(6) Location from which the food was shipped, and date and time (kept and sent)

Location Identifier	Location Description(*)	Shipment Date and Time
FP-PL-16	Fresh Processor, Plant #16	9/20/20 9:00 AM

(\*) This processor can shorten the location descriptions in individual records because the full set of information is listed in the processor's traceability program records.



## Processor's Shipping KDEs, Records to be Kept Only



§§ 1.1350(a)(7) and (8) Reference Record, and Transporter (kept only)

Reference Record Type and Number	Transporter Name
ASN 77777	XYZ Shipping Co.

### **Scenario Overview**





 Food Distributors receives salad kits from Fresh Processor

### The organizations they work with are:

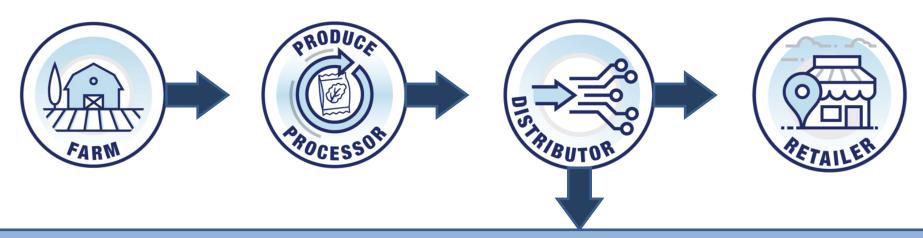
- Fresh Processor receives ingredients,
   processes and ships salad kits to Food
   Distributors
- Retailer receives salad kits from Food
   Distributors and sells salad kids to Consumers

### Food Distributors





### **Distributor's Traceability Program Records**



#### § 1.1315(a) Traceability Program Records

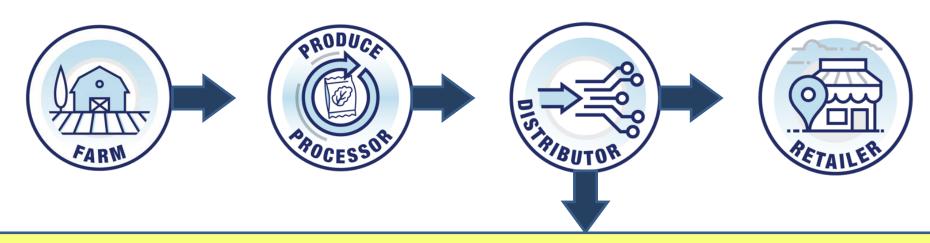
- Description of Reference Records
- Listing of FTL Foods shipped
- Other Information, Location Master Listing
- Other Information, Listing of FTL Foods Received

Abbreviated for time, please see Tomato Grower for detailed examples of program records





## **Distributor's Receiving KDEs**



#### § 1.1335 What records must I keep when I receive a food on the Food Traceability List

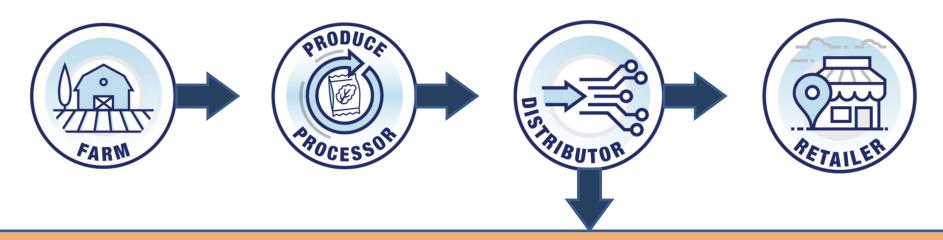
- Traceability Product ID and Description, Traceability Lot Code, Quantity and UOM
- Source Location ID and Description
- Recipient Location ID and Description, Receipt Date and Time
- Traceability Lot Code Generator Location ID and Description, Point of Contact
- Reference Record Type and Number and Transporter
- Import Entry Number if imported

Abbreviated for time, please see Processor's Shipping KDEs for detailed examples





## Distributor's Shipping KDEs, Product Information (Kept and Sent)



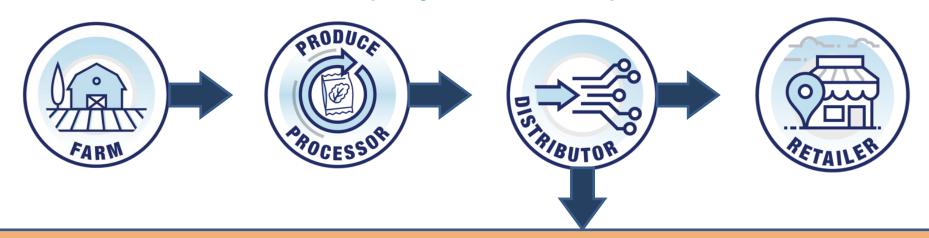
#### §§ 1.1350(a)(2) and (3) Product Information (kept and sent)

Traceability Lot Code	Quantity and Unit of Measure	Traceability Product Identifier	Traceability Product Description(*)
FPP16-091920	5 Cases	999999	Garden Salad Kit, 10 X 12 OZ (UPC: 9999999)

(\*) The distributor can shorten the product descriptions in individual records because the full set of information is listed in the distributor's traceability program records. Showing UPC in description is not a requirement, it reflects a common business practice.



## Distributor's Shipping KDEs, Traceability Lot Code Generator (Kept and Sent)



#### § 1.1350(a)(4) Traceability Lot Code Generator (kept and sent)

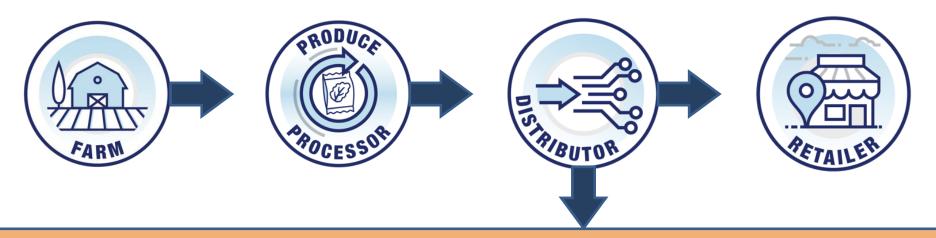
Location Identifier	Location Description (*)	Point of Contact Name	Phone	Email
FP-PL-16	Fresh Processor, Plant #16	Bob Brown	777-777-7778	bbrown@processor.com

(\*) The distributor can shorten the location descriptions in individual records because the full set of information is listed in the distributor's traceability program records.





## Distributor's Shipping KDEs, Ship-To Information (Kept and Sent)



§§ 1.1350(a)(5) Immediate subsequent recipient (kept and sent)

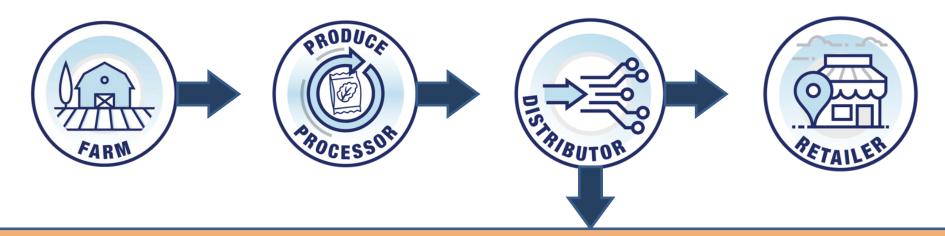
Location Identifier	Location Description(*)
RST-1052	Retailer, Store #1052

(\*) The distributor can shorten the location descriptions in individual records because the full set of information is listed in the distributor's traceability program records.





## Distributor's Shipping KDEs, Ship-From Information (Kept and Sent)



#### § 1.1350(a)(6) Location from which the food was shipped, and date and time (kept and sent)

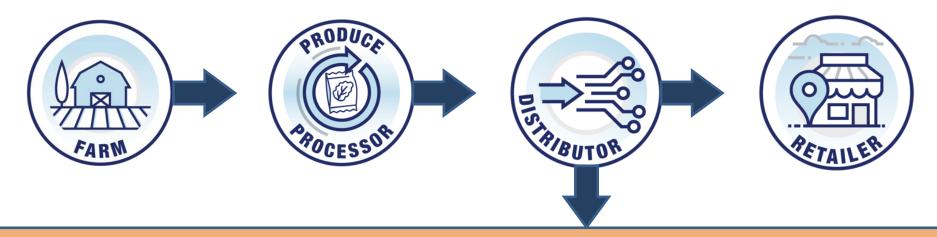
Location Identifier	Location Description(*)	Shipment Date and Time
DC-100	Food Distributors, DC #100	9/21/20 8:00 AM

(\*) The distributor can shorten the location descriptions in individual records because the full set of information is listed in the distributor's traceability program records.





### Distributor's Shipping KDEs, Records to be Kept Only



§§ 1.1350(a)(7) and (8) Reference Record, and Transporter (kept only)

Reference Record Type and Number	Transporter Name
POD 63264	Foodretail Trucking

### **Scenario Overview**





Fresh Processor – lot code generator for salad kits

• Retailer receives salad kits from Food Distributors and sells to Consumer.

Retailer





### **Retailer's Traceability Program Records**



#### § 1.1315(a) Traceability Program Records

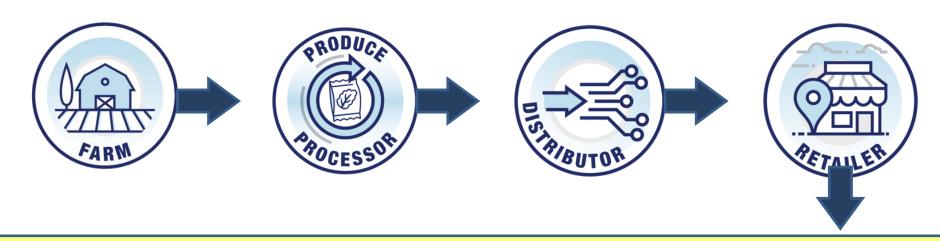
- Description of Reference Records
- Other Information, Location Master Information
- Other Information, Listing FTL Foods Received

Abbreviated for time, please see Tomato Grower for detailed examples of program records





### **Retailer's Receiving KDEs**



#### § 1.1335 What records must I keep when I receive a food on the Food Traceability List

- Traceability Product ID and Description, Traceability Lot Code, Quantity and UOM
- Source Location ID and Description
- Recipient Location ID and Description, Receipt Date and Time
- Traceability Lot Code Generator Location ID and Description, Point of Contact
- Reference Record Type and Number and Transporter
- Import Entry Number if imported

Abbreviated for time, please see Distributor's Shipping KDEs for detailed examples





### **Questions?**



**Program Records** 

**Growing KDEs** 

KDEs to Send To 1st Receiver

> Originator Harvester Cooling Packing

PRODUCES SOR

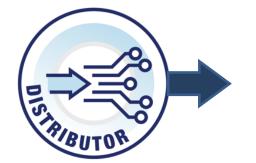
**Program Records** 

1<sup>st</sup> Receiver KDEs

**Receiving KDEs** 

Transformation KDEs

**Shipping KDEs** 



**Program Records** 

**Receiving KDEs** 

**Shipping KDEs** 



**Program Records** 

**Receiving KDEs** 

**Shipping KDEs** 

## U.S. FOOD & DRUG ADMINISTRATION

**CENTER FOR FOOD SAFETY & APPLIED NUTRITION**