

# Food Traceability Proposed Rule Overview

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# FDA Food Safety Modernization Act (FSMA):

## *Sec. 204 – Enhancing Tracking and Tracing of Food and Recordkeeping*

- **Pilot Projects – COMPLETED**
  - Coordinate with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak
- **Additional Recordkeeping Requirements – COMPLETED Proposed Rule**
  - Publish a notice of proposed rulemaking to establish recordkeeping requirements, for facilities that manufacture, process, pack, or hold foods that the Secretary designates
- **Designation of foods – COMPLETED Proposed Food Traceability List**
  - Designate foods for which the additional recordkeeping requirements are appropriate and necessary to protect the public health.
- **Public input – IN PROGRESS**
  - During the comment period in the notice of proposed rulemaking, conduct at least 3 public meetings

# FSMA 204(d) – Additional Recordkeeping Requirements for High Risk Foods

## Requirements shall... *(this list is not an exhaustive list)*

- Apply only to designated foods;
- Not require a full pedigree;
- Not require records of recipients of a food beyond the immediate subsequent recipient of a food (can only go one up);
- Not prescribe specific technologies for maintaining records
- Allow maintenance of records at an accessible location;
- Include a process by which a food may be removed from the designated list
- Be science-based



# The Case for Better Traceability



## We know:

- Consumers want to know more about their food.
- The food system and supply chains are changing at an accelerated pace.
- Regulatory approaches must continue to evolve.
- 1 step up and 1 step back is not enough

## Needs:

- Data standards
- Linking – connecting the dots on how food moves through the marketplace
- Interoperability and interconnectivity
- Improved communications
- Rapid identification of sources of contamination
- To limit the scope of recalls



## What would the Food Traceability rule do?

Would require covered persons to maintain records for foods on the Food Traceability List to support more efficient and accurate traceability of potentially contaminated food

# Background

- **Proposed Rule:** Published September 23, 2020
- **Public Comment period ends:** January 21, 2021 (120 days after publication)
- **Virtual Public Meetings:** Nov 6, Nov 18, Dec 2
- **Final Rule:** Under consent decree, FDA must submit a final rule to the Office of the Federal Register by November 7, 2022



## Benefits of the Food Traceability proposed rule

- Potential to reduce foodborne illnesses/deaths
  - Faster identification of source of contamination
  - Rapid removal of contaminated food from market
- Potential to limit the scope of recalls
- Harmonized information
  - Establish linkages along supply chain more quickly
- Aligns with current industry approaches
- Would enhance ability to conduct root cause investigations to identify and apply lessons learned from outbreaks
- Greater transparency + supply chain intelligence

# Key Concepts of the Proposed Rule



Touches the whole supply chain from farms and facilities to retail food establishments



Includes both foreign and domestic entities



Only applies to certain foods



Some exemptions and partial exemptions



Co-proposal on Retail Food Establishments



# Proposed Requirements

## Critical Tracking Events

Growing, receiving, transforming, creating, and shipping are Critical Tracking Events (CTEs) for which records would be required.

## Key Data Elements

Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

**The KDEs required would vary depending on the CTE that is being performed.**

The records required at each CTE would need to contain and link the traceability lot code of the food to the relevant KDEs.

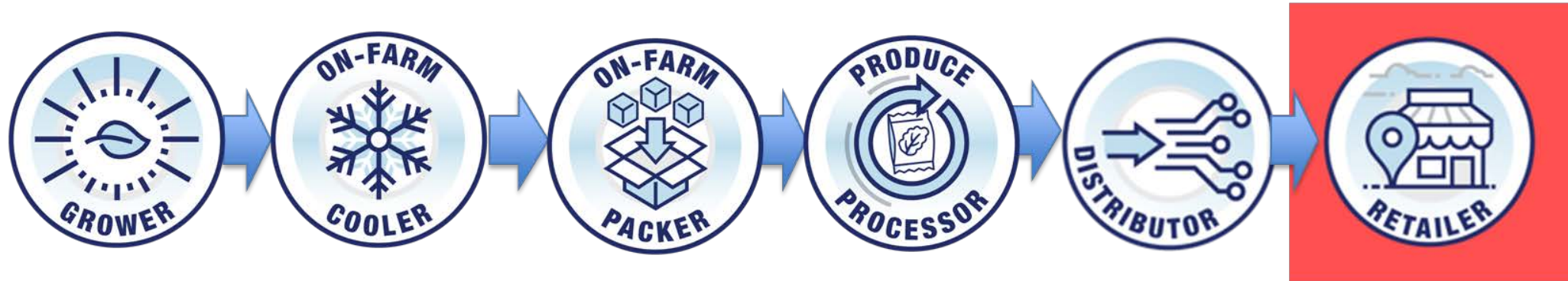


## Emphasis on....

- Traceability Lot Code
  - Important for making linkages within a firm and through a supply chain
  - Stays the same as a product moves through the supply chain until a transformation of the food occurs
  - Along with the information on the traceability lot code generator, helps FDA to quickly go back to the entity within the supply chain that originated, created, or transformed the product
- Enables FDA to “skip” points that minimally handle the product



# Instead of going to each point in the chain...

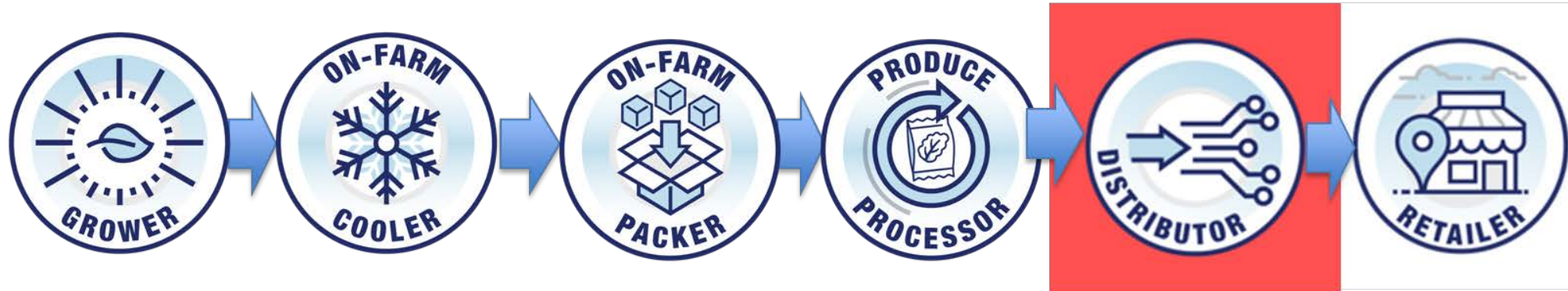


- **At each point in the chain:**

- Asking questions on the product received
- Gathering non-standardized information in paper and/or electronic format
- Different terminology and lack of connectivity
- Asking the firm clarifying questions



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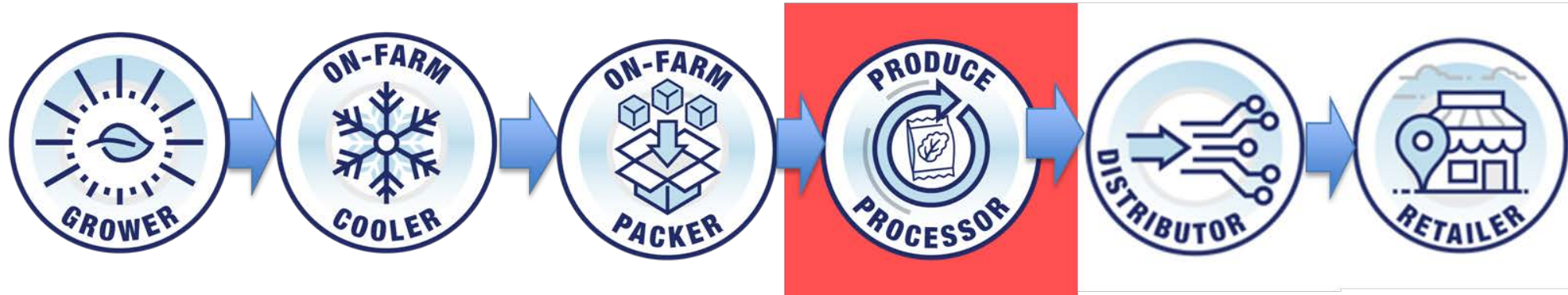


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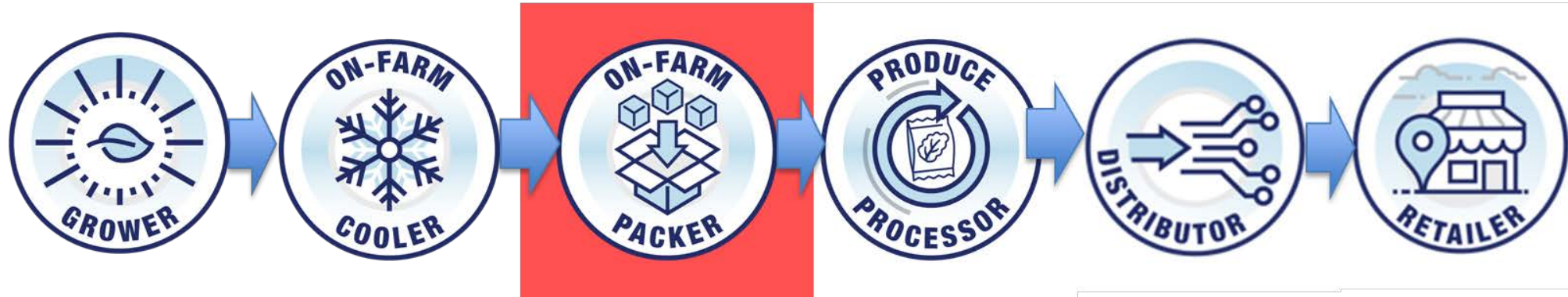


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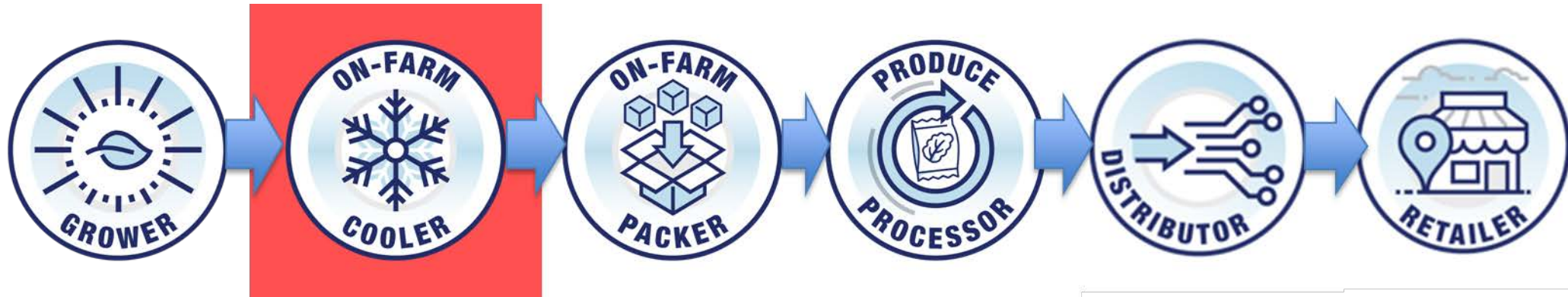
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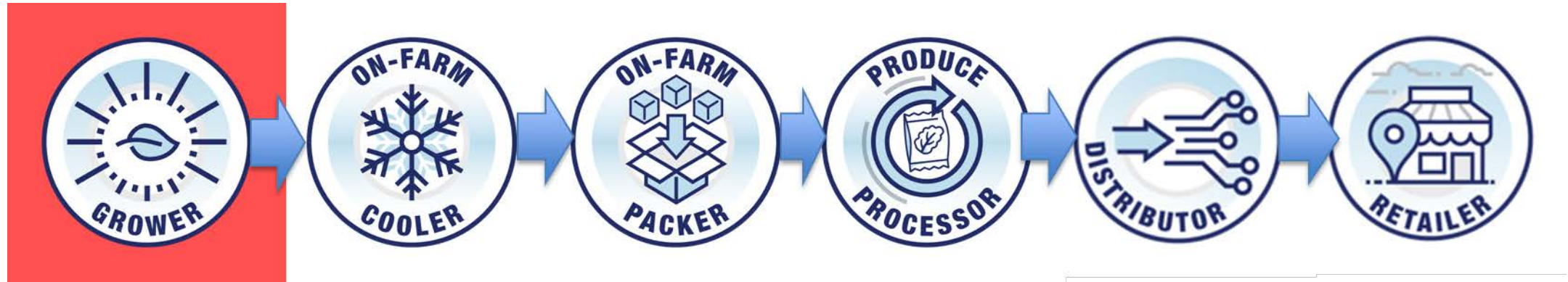


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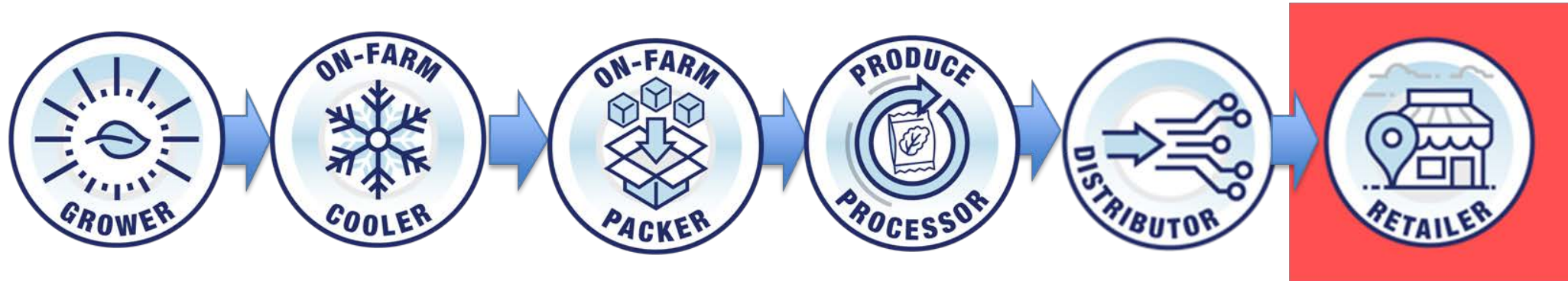
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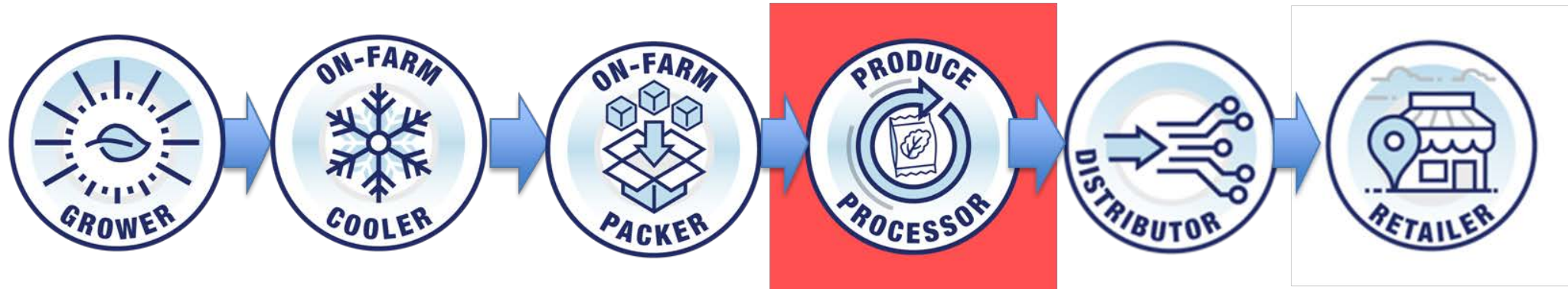


- **Vision:**

- Asking for **KDEs related to an entity's CTEs** for a certain time period
- Gathering **standardized** information in paper and/or electronic format
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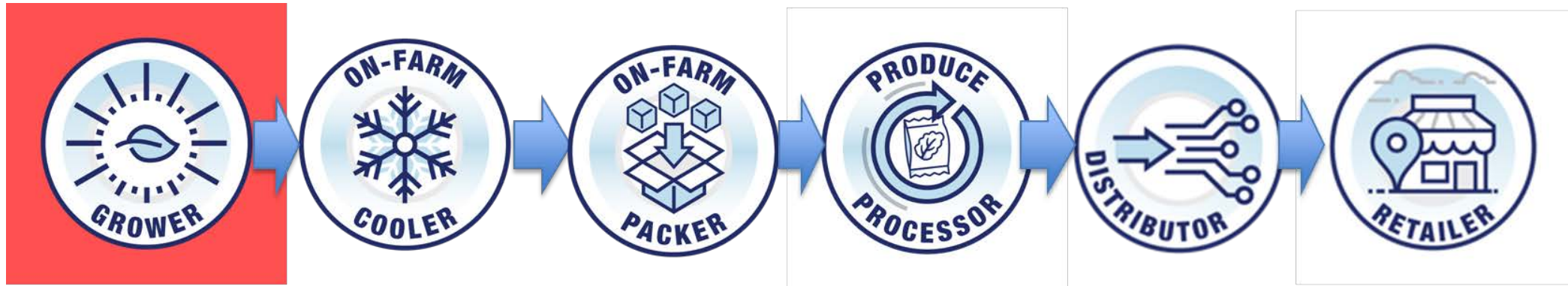


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# Advancing Traceability



- Food Traceability proposed rule is a first step
- Will help to harmonize Key Data Elements and Critical Tracking Events across industry
- New Era for Smarter Food Safety will build on this foundational work
- Ultimate goal is end-to-end traceability throughout the food system



# Plan for today

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Perspective from CDC and FDA's Coordinated Outbreak Response and Evaluation Network

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Presentations on sections of the proposed rule

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Application of CTE/KDE approach

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Clarifying questions

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Hear from state and industry partners

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Opportunity for public comments



**FDA**

**U.S. FOOD & DRUG**

**ADMINISTRATION**

**CENTER FOR FOOD SAFETY & APPLIED NUTRITION**