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# FDA FSMA Proposed Rule for Food Traceability

A Win for Profitability and Transparency



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# Meet the Speakers

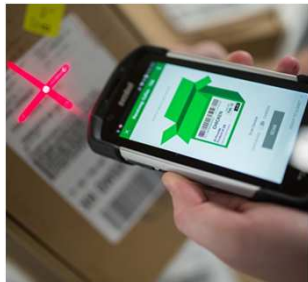


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# FSMA 204: Enhanced Traceability Recordkeeping Requirements



## Enhanced Traceability

FSMA 204 lays the foundation for end-to-end food traceability, extending beyond the current “one-up and one-back” requirement.



## Designated High-Risk Foods

Listing of a wide variety of produce, dairy, seafood, and ready-to-eat products that would require traceability records.



## Harmonized Approach

Reviewed existing standards, industry initiatives and current approaches.

# FSMA 204 Proposal - Key Areas

- Traceability Program Records
- Roles and Responsibilities
- Exemptions
- Data Attributes
- Compliance Dates
- Economic Analysis



*Image: FDA New Era of Smarter Food Safety*

# Who is Affected?

Proposal is a requirement for those who:

- Manufacture
- Process
- Pack or
- Hold foods on the Food Traceability List (FTL)

The additional recordkeeping requirements would apply not only to foods specifically listed on the FTL, but also to foods that contain foods on the list as ingredients.

Includes domestic and foreign entities





# What are the Proposed Requirements?

Traceability records must be maintained, legible and stored - and must be provided to the FDA **within 24 hours.**

## Critical Tracking Events:

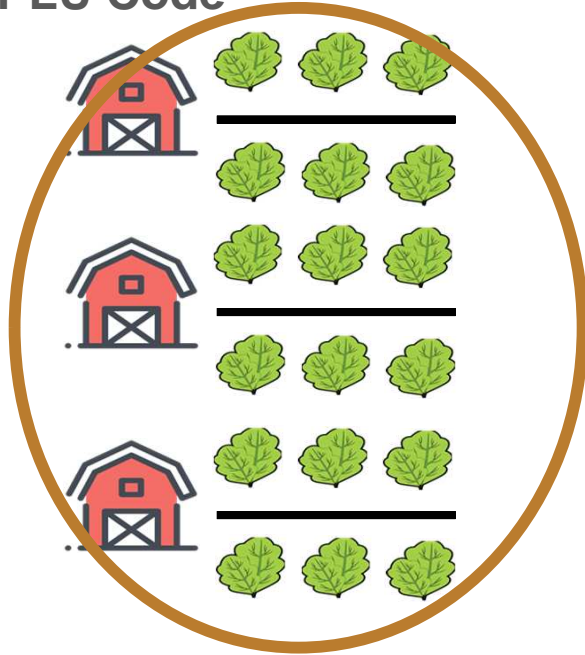
- Growing
- Receiving
- Creating
- Transformation
- Shipping



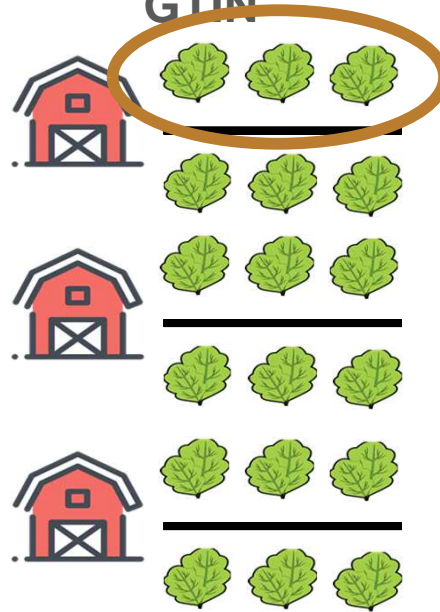


# Power of Traceability

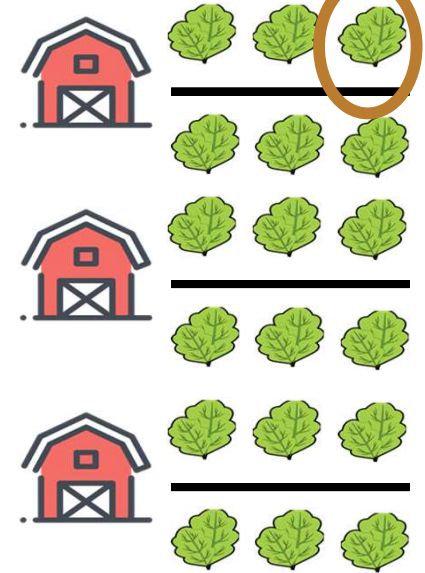
PLU Code



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# Making Sense of the Data

It's all about Events and Attributes

## Critical Tracking Events (CTE)

An event in the supply chain of a food involving the growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food.

## Key Data Elements (KDE)

The data attributes or information associated with a Critical Tracking Event for which a record would have to be established and maintained.

# Single Ingredient CTE

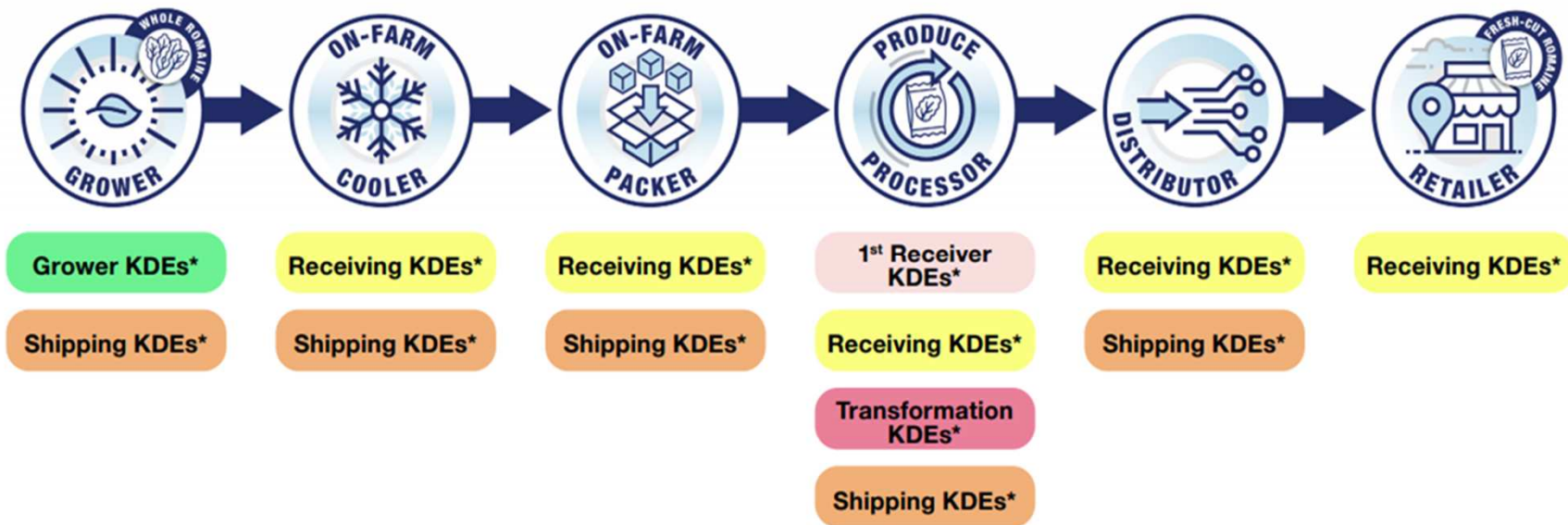


Image: FDA FSMA Proposed Rule for Food Traceability

# Multiple Ingredient CTE

## Peanut Butter and Peanut Butter Crackers (No kill step)

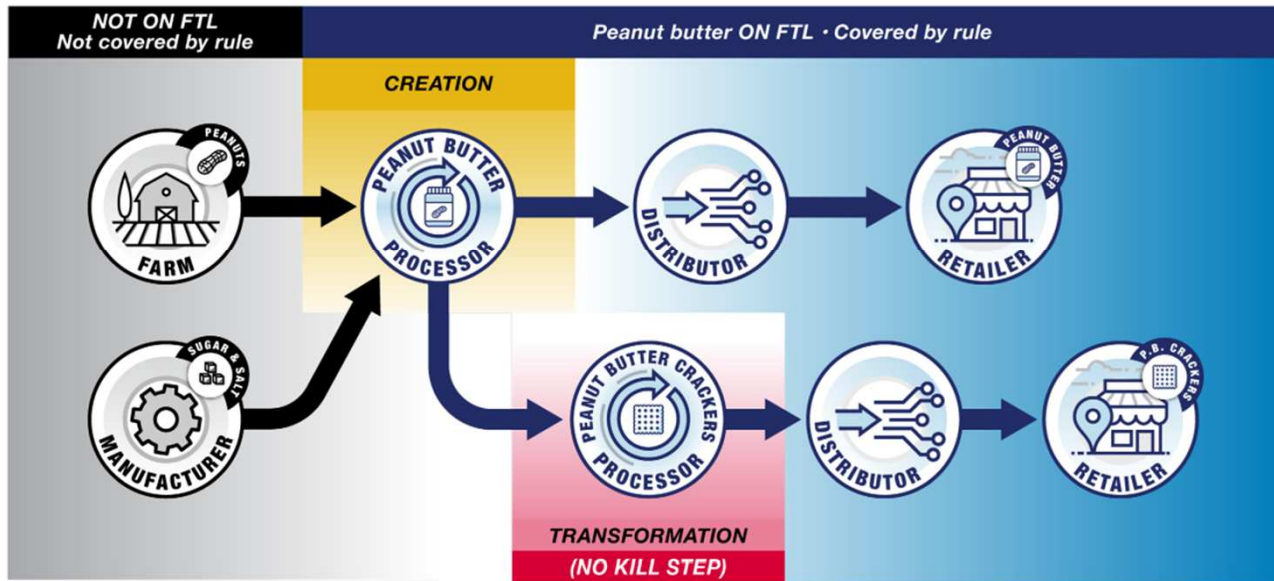


Image: FDA Creation and Transformation



# Proposal Aims to Help the Food Industry



## Standardize

Data elements and information that companies must establish and maintain across the supply chain.



## Define

Define the information to be shared with the next entity in the supply chain.



## Facilitate

Rapid and accurate traceability capture required traceability data.



## Act

Leverage traceability data needed to prevent or mitigate foodborne illness outbreaks.

# Key Dates



## Timeline:

Sept 2020

Published to Federal Register

Jan 21, 2021

Public Comments Due

November 2022

Finalized Rule

January 2025

Compliance Date For All Parties

## FDA Public Meetings on Food Traceability Rule:

Online meetings held 11/6, 11/18 and 12/2 2020

Recordings and transcripts from all 3 meetings available on the FDA website

# Get Involved!

The FDA continues to update their website with extensive documentation

Subscribe to their updates to ensure you are aware of the latest tools and documentation

Participate in industry workgroups





# GS1 US EPC Extended Attributes Group

**Charter Statement:** “Working within the GS1 system of standards, simplify the capture of traceability attributes encoded in the EPC/RFID data carrier in the Foodservice and Retail Grocery industries.”

**Scope:** “This workgroup will fully define the problem and business requirements, weigh possible solutions, and create an industry-specific guideline that defines near-term guidance in a manner that will not hinder the community or industry.”

**Contact:** Jonathan Gregory, Director, Community Engagement

[jgregory@gs1us.org](mailto:jgregory@gs1us.org)

Or request to join the group from the GS1 US Community Room

<https://community.gs1us.org/kws>



# Contact Us



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# Questions



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**Don't forget to complete the session  
survey in the mobile app**

**We need your input**

# Thank you for Attending



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**Presentations will be available on-line soon. You will receive an email with a link when they are available.**