



TRACEGAINS WEBINAR

Traceability and Transparency

The Next Wave of Change for CPG Supply Chains

July 13, 2022

Meet Your Moderator



Kristen Goodale
Marketing Coordinator



Meet Your Speakers



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Founder | The Food Leadership Group

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Traceability and Transparency

The Next Wave of Change

Bryan Armentrout

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Who am I?



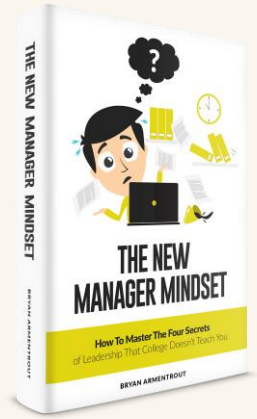
WhiteWave



Leprino Foods®



BONGRAIN SA

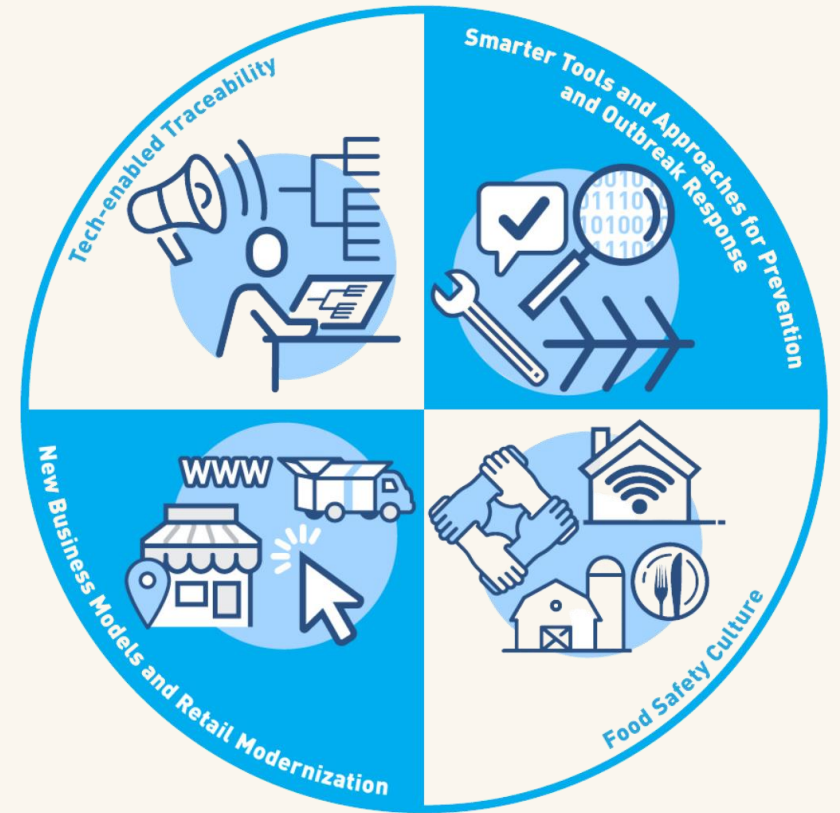


CONSUMER BRANDS ASSOCIATION



Agenda

- Focus/ Objective
- Typical Recall Scenario
- Regulatory Background
- Enhanced Traceability Proposed Rule
- What you need to know
 - Rules and Terminology
 - Examples
- Next Steps
- Enhanced Traceability Decision Tree
- Supply Chain Disruptions
- Q&A



Focus

- Multitasking does not work
- Your time is valuable, invest it wisely
 - ✓ Turn off Facebook
 - ✓ Kick out the cat
 - ✓ Close the door
 - ✓ Take notes
 - ✓ Ask questions



Objective

- The goal is NOT to recite the proposed regulation
- The goal IS to understand FDA desired outcomes
- My intention is to help you plan your next steps and integrate in current supply chain issues



Typical Recall Scenario

- Potential issue identified
- Company contacted
- Internal Investigation
- Recall Decision
- FDA Notified/ RFR
- Crisis Management Activation
- Communication/ Investigation
- Traceback/ Reconciliation
- Disposition/ Close out



FDA Traceback/ Supply Chain Challenges

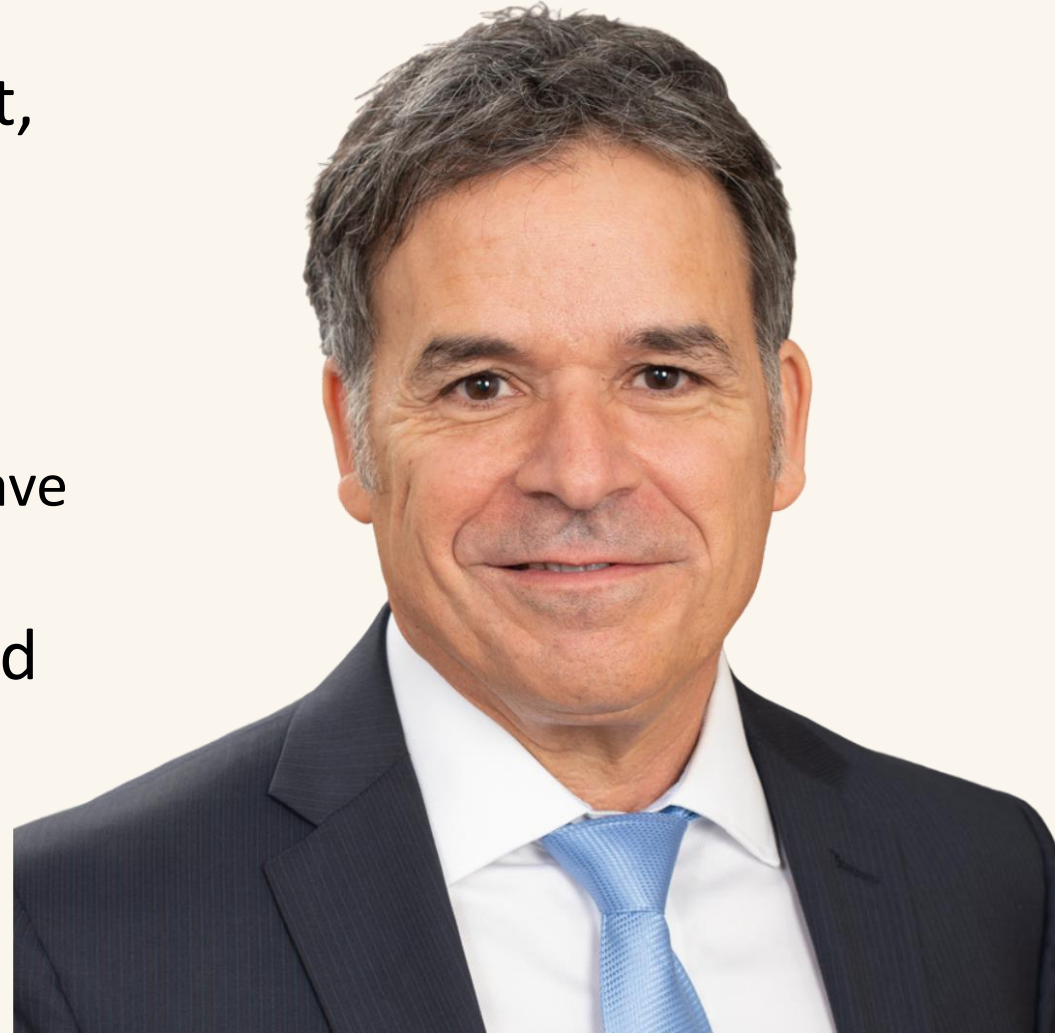
- Fast action is required
- Poor consumer recollection of consumption history/ specific information
- Multiple produce varieties/ multiple ingredients
- Multiple sources of same product at points of sale
- Poor record-keeping at firms within the distribution chain
- Lack of a rapid and rigorous mechanism to link shipments from farm to fork
- Varying tracing data across the supply chain
- *New issues have impacted supply chain reliability*

FDA is very frustrated with the current system

Compliance Requirements

- I am already FSMA compliant with my product, so this doesn't apply to me...
- If you are "high risk" it does!
 - You will need MORE traceability than what you have

"One forward and one back is no longer good enough."



Proposed Traceability Rule

- Who does this impact?
- High risk items
- Size of company
- Exemptions



Proposed Traceability Rule

- FSMA regulated products
 - Domestic and Imported
- FSMA Section 204 – Regulation development
 - Industry Pilot Programs - *Completed*
 - Record Keeping – *Proposed Rule Completed*
 - High Risk Foods – *List compiled*
 - Public Input – *Three public meetings - Completed*
 - Final Rule – November 7th, 2022
 - Effective 60 days after publication – 2 years for compliance

What you need to know

- Does this apply to you?
 - Exemptions are in place for the new recordkeeping requirements
 - Waivers
 - Raw Agricultural Commodities
 - Charitable Food Establishments
 - Personal consumption
 - Food with a kill step
- Is my product a High-Risk Food?
 - FDA Supply Chain Hazard Analysis



Food Traceability List (FTL) for High-Risk Foods

- Cheeses (not hard)
- Shell eggs
- Nut butter
- Cucumbers
- Herbs
- Leafy greens
- Melons
- Peppers
- Sprouts
- Tomatoes
- Tropical Tree Fruits
- Fruits and Vegetables (fresh cut)
- Finfish/ Smoked Fish
- Crustaceans
- Mollusks, bivalves
- RTE Deli Salads

Who is the First Receiver?

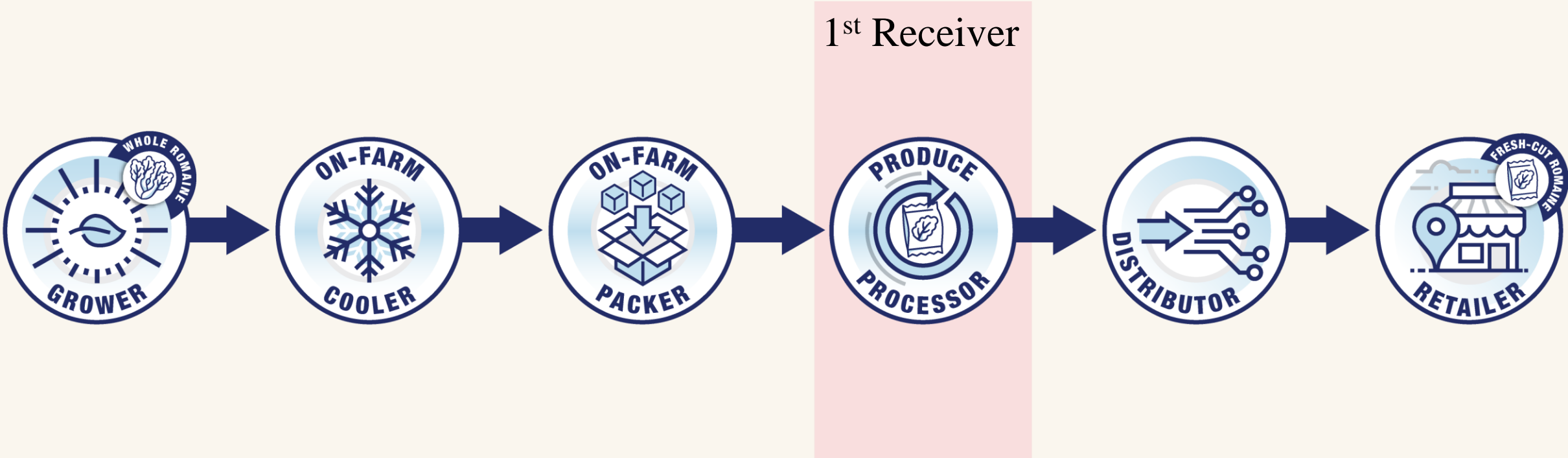


Key Terminology – Food Traceability List (FTL)

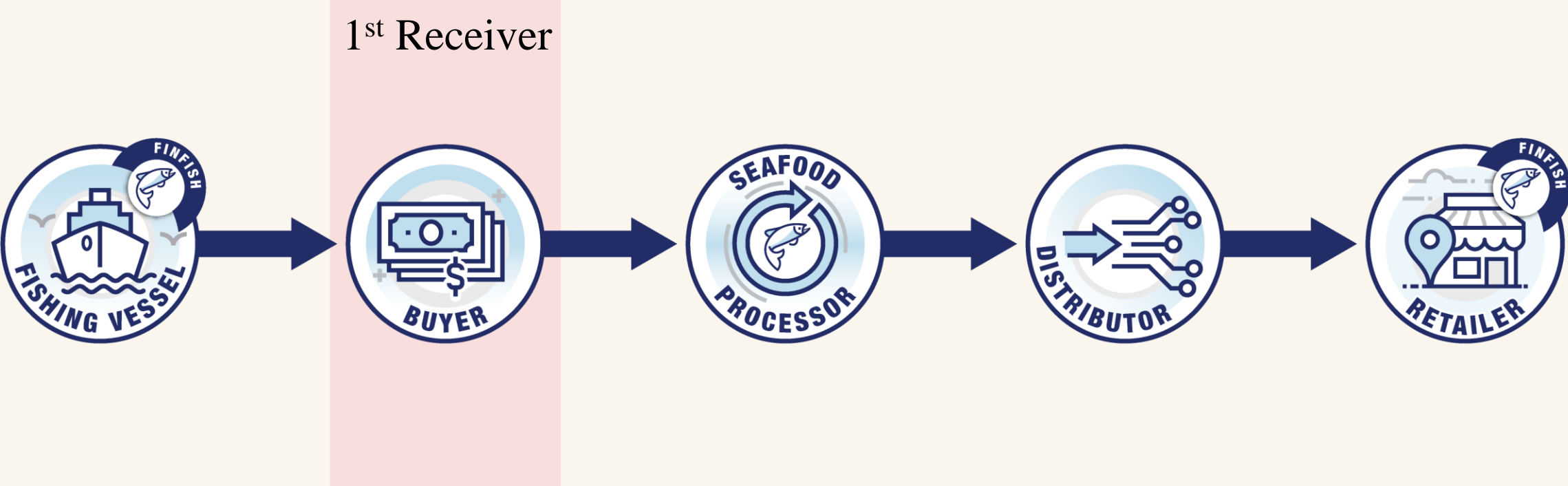
- **First Receiver**

- The first person (other than a farm) who purchases and takes physical possession of a food on the Food Traceability List (FTL) that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested.
- Any entity except a farm
- Must maintain Key Data Elements (KDE) and Critical Tracking Event (CTE) data
- If a farm sells FTL foods, they must identify as a farm for those downstream
- A first receiver may need to **establish a traceability lot code** for a food if they receive food from an originator without a traceability lot code

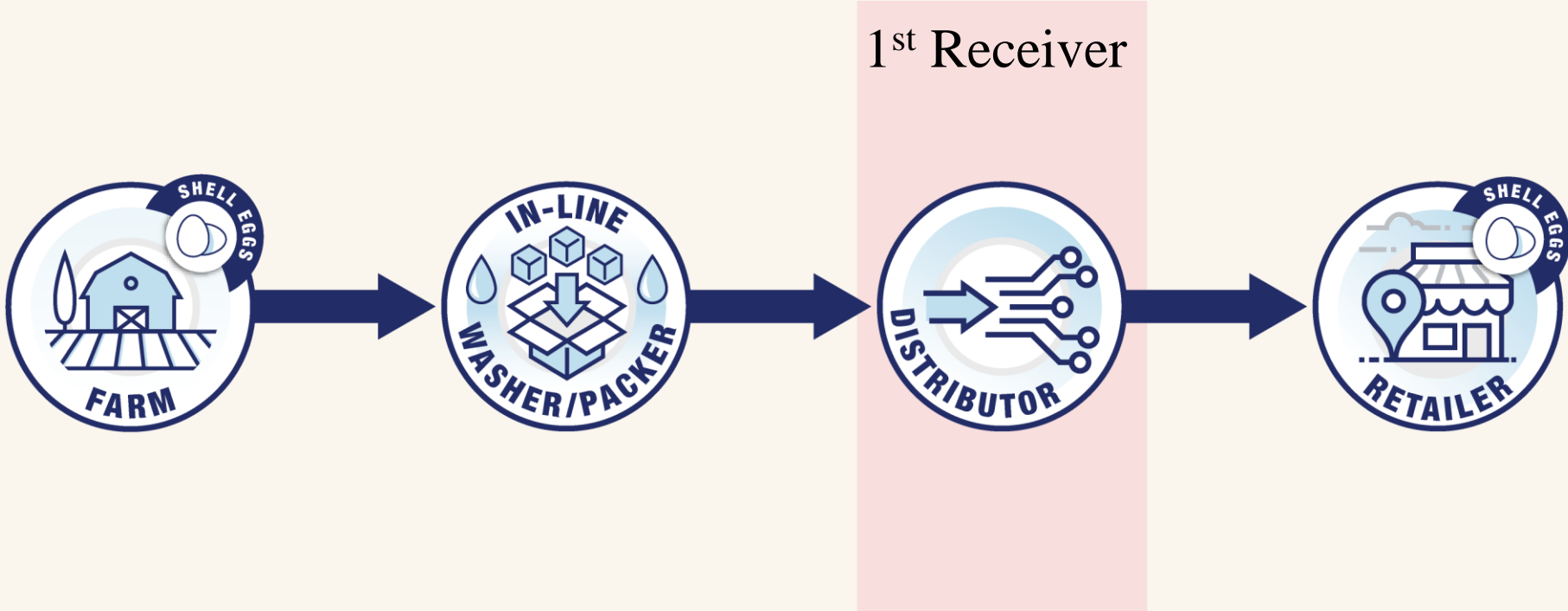
Fresh- Cut Romaine



Finfish



Shell Eggs



First Receiver Responsibilities

- Create/ identify the Lot Code for Traceability
 - Moves forward with the product
- Identify Critical Tracking Event (CTE)
 - Step for which records are required
- Determine Key Data Elements (KDE)
 - Records needed for the CTE



Key Terminology – Food Traceability List (FTL)

- CTE: Critical Tracking Event
 - Growing, receiving, transforming, creating, and shipping for which records would be required.
- KDE: Key Data Element
 - Required records would need to contain specific Key Data Elements. 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 KDE's.

Traceability Lot Code

- 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 with the supply chain that originated, created, or transformed the product.
 - Enables FDA to “skip” points that minimally handle the product.

Creation and Transformation

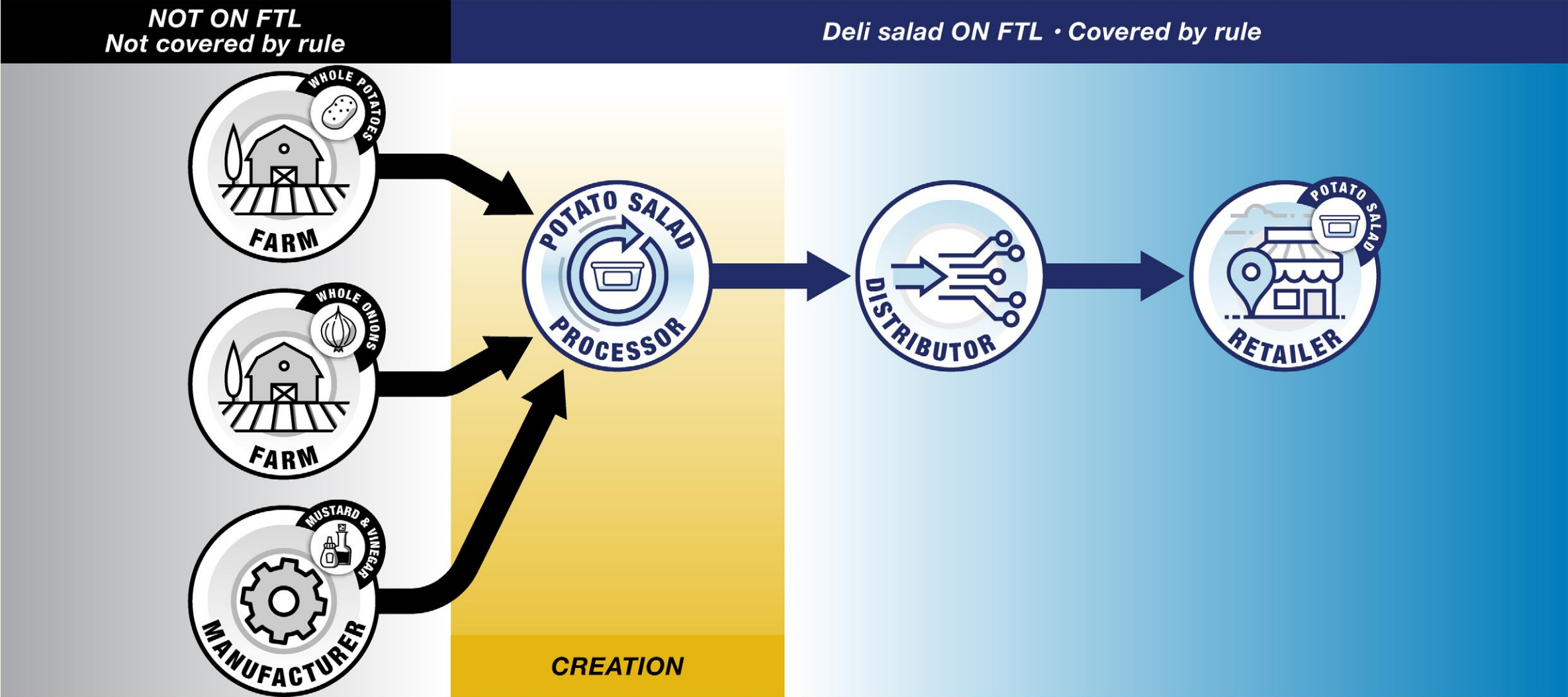
- Creation: Making or **producing a food on the FTL** using only ingredients that are NOT on the FTL. Creating does not include originating or transforming a food
- Transformation: An event in a food's supply chain that involves **changing a food on the FTL**, its package, and/or its label such as by combining ingredients or processing a food. Transformation does not include the initial packaging or a single-ingredient food or creating a food.

Key Parameters for You



- Do I have products or ingredients on the FTL?
- What in the supply chain requires tracking?
- What records do I need?
- How will I maintain traceability of the lot code in the supply chain?
- Who else needs to know this in the supply chain?

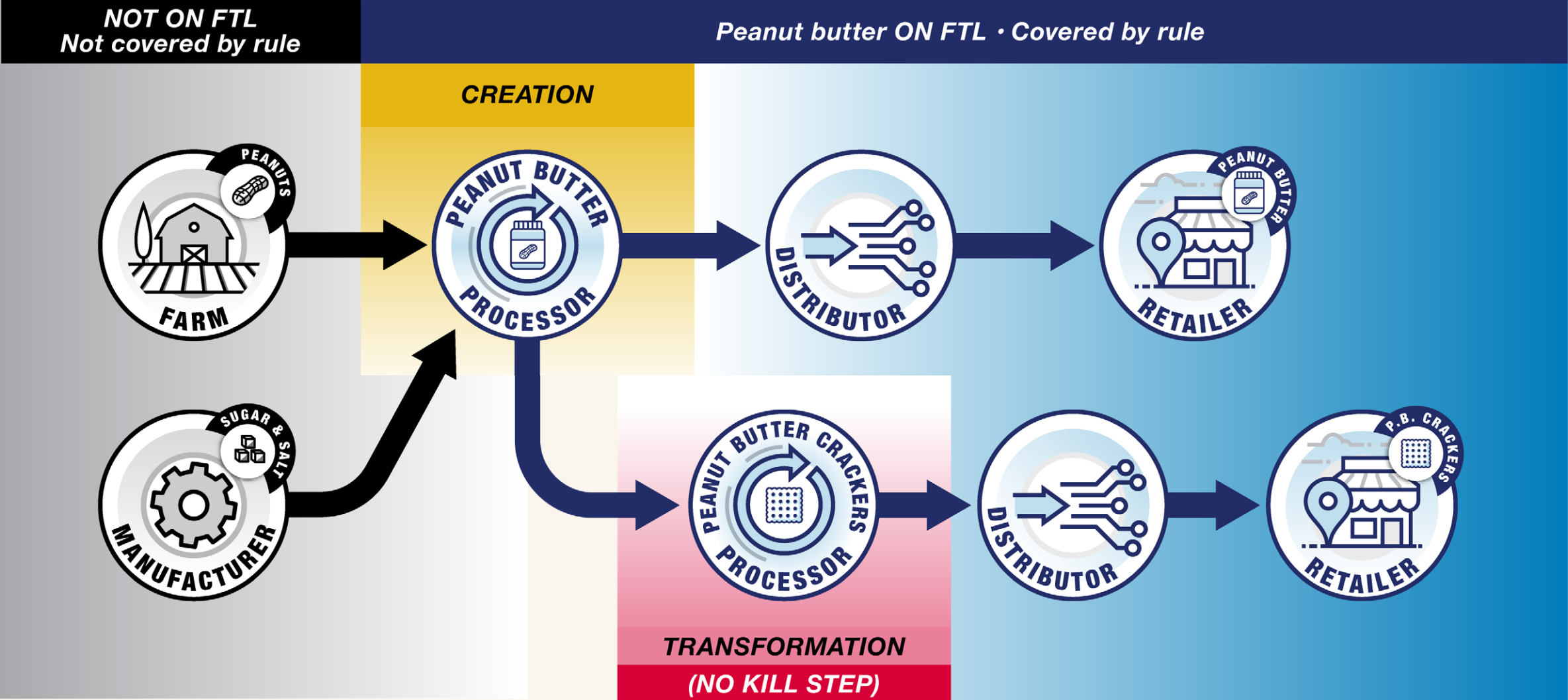
Creation – Potato Salad



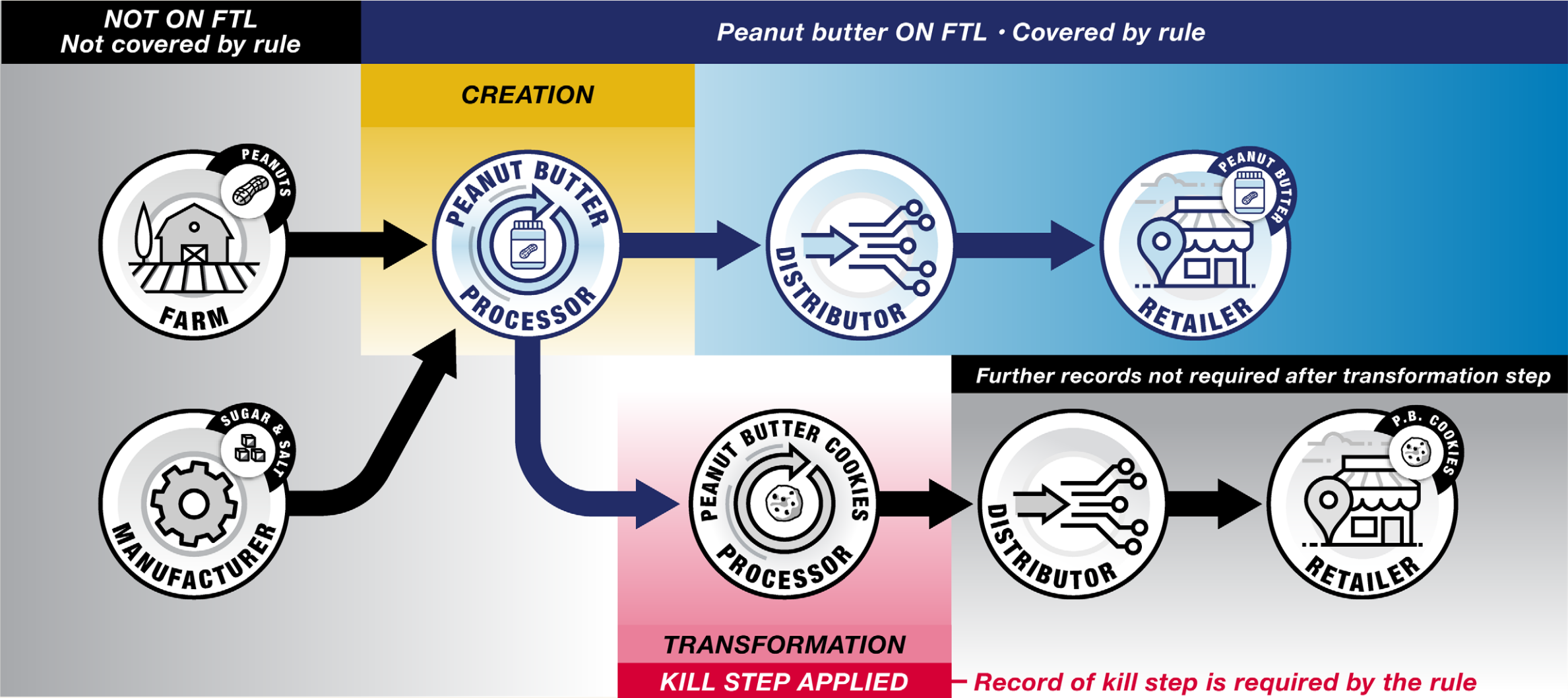
Peanut Butter Example

- Created: Ingredients (peanuts, salt, sweeteners, emulsifiers) not on the list but the product is on the FTL (Nut Butters) – See Potato Salad
- Transformed: Peanut Butter Sandwich Crackers are made from a food on the FTL (Nut Butters) with other ingredients (Crackers) and must provide traceability information. The risk is carried downstream (no kill step)
- Note: If you have a product that transforms an FTL with a kill step, and provided you keep records, recordkeeping does not apply for traceability.

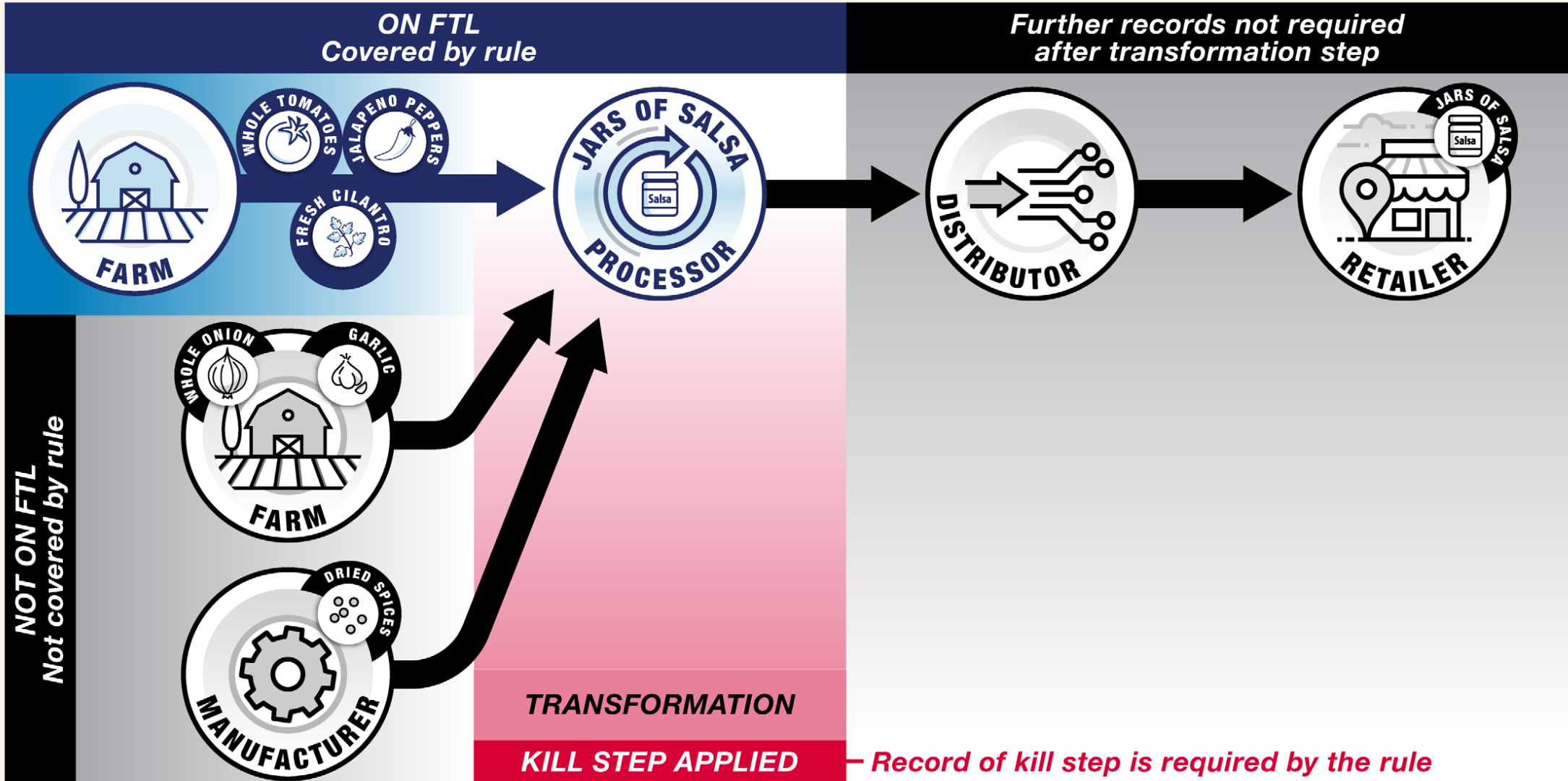
Peanut Butter Crackers



Peanut Butter Cookies



Jars of Salsa

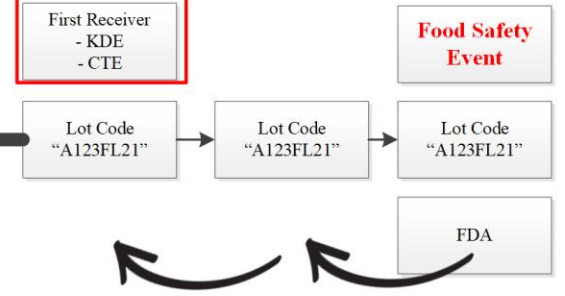
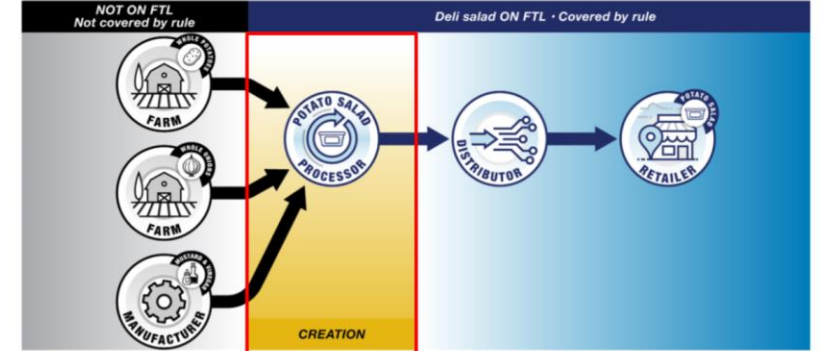
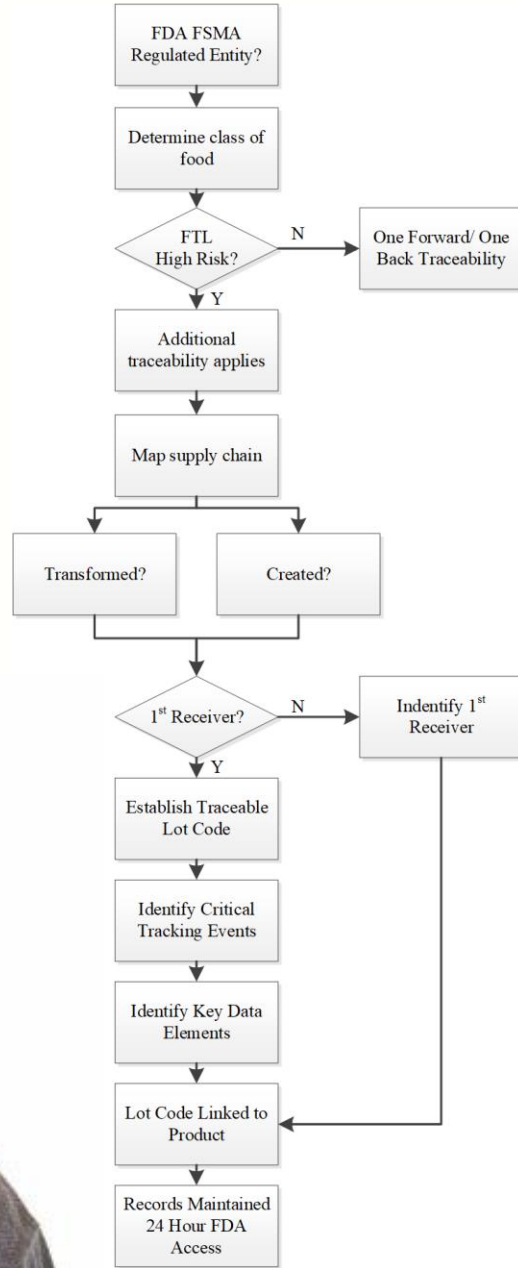


Summary of Next Steps

- Do I fall under **FSMA** jurisdiction?
- Am I part of a **high-risk food** product supply chain?
 - Who in the process is a participant or not?
- Do **exemptions** apply?
- Am I defined as a First Receiver?
 - What Critical Tracking Event applies?
 - What Key Data Elements are needed?
 - Do I need to set up a transferrable lot code?
- Do I **Create** or do I **Transform**?

The Food Leadership Group

Food industry risk management specialists



Supply Chain Transparency

- Disruptions are now common
 - Ukraine
- Product Reformulation
- Food Fraud and Identity
- FSVP compliance

- *How does this fit with enhanced traceability?*



Questions?

- **Action Plan**

- Proposed Rule Compliance
- Supply Chain Conformance – New Risks
- First Receiver Determination
- Supply Chain Outreach/ Contacts
- Plan For Compliance
- Train, Test And Execute

- **Food Safety Foundation**

- [Locals Group Promo Code](#)

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TraceGains Network



**Freedom from tracking
down suppliers and requesting
information or documents**

46K+

Supplier Locations

530K+

Items & Ingredients

3M+

Supplier, Item & Ingredient Documents

150+

Standardized Online Forms

130+

Supplier Countries

Supply Chain Agility in Practice

Bringing People and Information Together to Work Smarter

Research & Development

- Quickly find ingredients & raw materials with technical specs
- Digitally model ingredient variations to meet product claims before physical testing



Suppliers

- Post documents and data one time for multiple customers
- Find new markets through TraceGains Gather™ marketplace

Regulatory

- Immediately address claims, labeling issues, and more
- Eliminate downstream delays

Procurement

- Accelerate supplier diversity
- Connect with alternative Suppliers

Quality

- Streamline ingredient & Supplier approval processes
- Prequalify new ingredients and suppliers
- Support rapid formula iteration

Our Solution

A Standard, Centralized and Digitized Approach to Controlling the Verification of Materials and Ingredients

Industry Standards for Data Collaboration



INDUSTRY STANDARD DATA

Digitization and Automation



NEW PRODUCT DEVELOPMENT SUITE

Supplier Management

The definitive industry solution for ingredient supplier documentation and data.

THE PROBLEM

You need vast amounts of supplier documentation to run your business.

WHY IT MATTERS

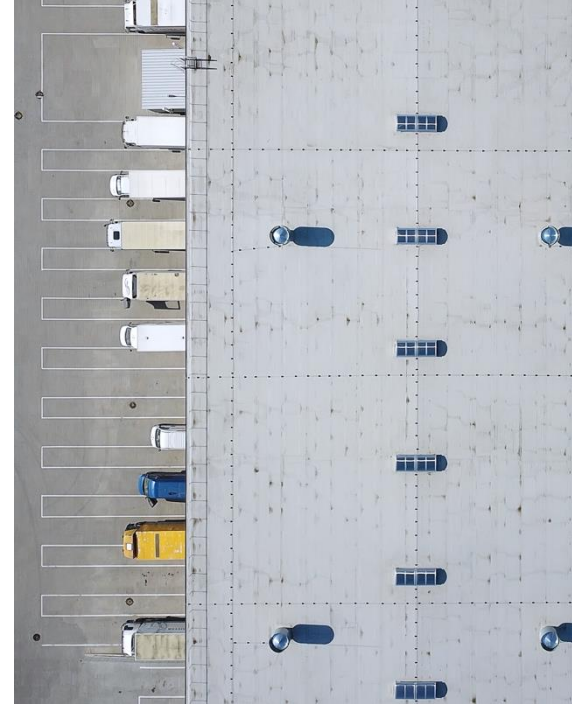
Cumbersome and repetitive document management slow down sourcing.

THE SOLUTION

Digital documents and data enable re-use, insights and automation.

THE TRACEGAINS DIFFERENCE

Powered by almost 20,000 suppliers in the TraceGains supplier ecosystem.



Market Hub

(TraceGains Gather™ MarketPlace)

The industry's leading supplier and service ecosystem, powered by TraceGains Network.

THE PROBLEM

The world is changing too fast for traditional sourcing.

WHY IT MATTERS

Fast, flexible sourcing is a winning strategy.

THE SOLUTION

Build agility through TraceGains Network.

THE TRACEGAINS DIFFERENCE

A growing marketplace of almost 20,000 suppliers and service providers in 130 countries.



Specification Management

Collaboratively author, publish, and update raw material and finished goods specifications.

THE PROBLEM

Manual and error-prone processes slow down collaboration and add risk.

WHY IT MATTERS

Quality, Production, and Time-to-Market all depend on solid specification processes.

THE SOLUTION

Bring all parties together in a collaborative digital environment.

THE TRACEGAINS DIFFERENCE

Real-time digital collaboration powered by TraceGains Network.



Smart Alerts

Real-time fraud and regulatory risk monitoring for your supply chain.

THE PROBLEM

Critical risk data that lives externally may not be there when you need it.

WHY IT MATTERS

Fraud, allergens, contamination, foreign material, recalls and bad actors.

THE SOLUTION

Configurable alerts from the industry's most authoritative sources, always up to date.

THE TRACEGAINS DIFFERENCE

Customized alerts driven by the needs of your business, and there when it matters most.



Value Across the Supply Chain

TraceGains brings people and information together.

- **R&D** can quickly find ingredients and raw materials **and digitally model variations**.
- **Regulatory departments** can address and manage claims, labeling issues, and another compliance-related requirement proactively.
- **Quality** can manage the ingredient and supplier approval process and prepare and share specs.
- **Procurement** can identify suppliers and estimate pricing, identifying alternate suppliers if needed.
- **Suppliers** can ensure safe items and ingredients seamlessly enter your supply chain.
- **Co-Manufacturers and Co-Packers** can connect with brands via TraceGains MarketPlace, with Finished Goods Specs Coming Soon.



TraceGains Export Tools and API's



- ✓ Pass Data Back And Forth From ERP Or PLM Systems To TraceGains
- ✓ Connect all systems of record.

Delivers complete supply chain transparency with a single pane of glass



Thank You

Together we do more