



Looking Forward and Looking back

How companies can establish a Robust and Compliant Traceability Program

CELEBRATING
25 YEARS
Produced by **FoodSafety**
MAGAZINE

Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204)

May 9, 2023
Food Safety Summit

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CFSAN, FDA



Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, unless an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms	Certain types of processing
Commercial raw agricultural commodities (RACs)	Personal consumption, testing, food for specific consumers
Foreign means production facilities	Other
Small food processors (SFPs), restaurants	



Subpart J – “one up, one back”



- Transporters and “non-transporters” of food
- Immediate previous source and immediate subsequent recipient of food products
- Exempts farms and restaurants

What will the Food Traceability Rule require?



- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
- Covers the entire food supply chain
- Includes both foreign and domestic entities

Common questions on coverage

- Foreign entities?
- Farms?
- Importers?
- Aquaculture farms?
- Brokers?
- Wild-caught seafood?
- Distributors?
- Manufacturers?
- Restaurants?
- Repackers?
- Retail Food Establishments?
- Warehouses?
- Airline caterers?

If you manufacture, process, pack, or hold foods on the FTL, you are covered

***Full or partial exemptions may apply for your situation**

Exemptions

Farms

- Certain small produce farms
- Certain small shell egg producers
- Certain other small RAC producers
- Certain food produced + packaged on farm
- Farms selling food directly to consumers

Commingled raw agricultural commodities (RACs)

- Certain commingled RACs (not fruits & vegetables)
- Certain RACs that will be commingled

Fishing vessels, molluscan shellfish

- Owner/operator/agent in charge of a fishing vessel
- Raw bivalve molluscan shellfish

Retail food establishments (RFEs), restaurants

- Certain small RFEs + restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on ad hoc basis

Certain types of processing

- Produce and shell eggs that receive certain processing
- Exemptions related to a kill step
- Exemptions related to changing a food to a form not on the list

Personal consumption, holding food for individual consumers

- Personal consumption
- Holding food for individual consumers

Other

- Produce listed as “rarely consumed raw”
- Farm-to-school/farm-to-institution programs
- Foods regulated by USDA
- Transporters of food
- Non-profit food establishments
- Food for research or evaluation

Exemptions Tool

Exemptions to the Food Traceability Rule

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Farms

Certain types of processing

Commingled raw agricultural commodities (RACs)

Personal consumption, holding food for specific consumers

Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants



Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh and frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh and frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated and frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh and frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh and frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	



Food Traceability List

- Foods specified as “fresh” on the FTL
- Fresh FTL foods used in multi-ingredient foods
- Changing the form of the food
- Foods not specified as “fresh” used in multi-ingredient foods
- Applying a kill step to the food

Updating the Food Traceability List

- We anticipate updating the list approximately every 5 years
- We will publish a notice in the *Federal Register* with the proposed changes, providing an opportunity for public comment
- A second *Federal Register* notice will state the final decision on any changes being made
- Additions to the list would become effective 2 years after this second *Federal Register* notice, unless otherwise stated
- Deletions from the list would be effective immediately

CTE and KDE Framework

The role of the entity in the supply chain defines the data it must keep and share

Critical Tracking Events

Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming 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 KDEs to the traceability lot.

Emphasis on...



Keeping and sharing KDEs



Traceability Lot Code (TLC)



Traceability Lot Code Source (TLC Source)

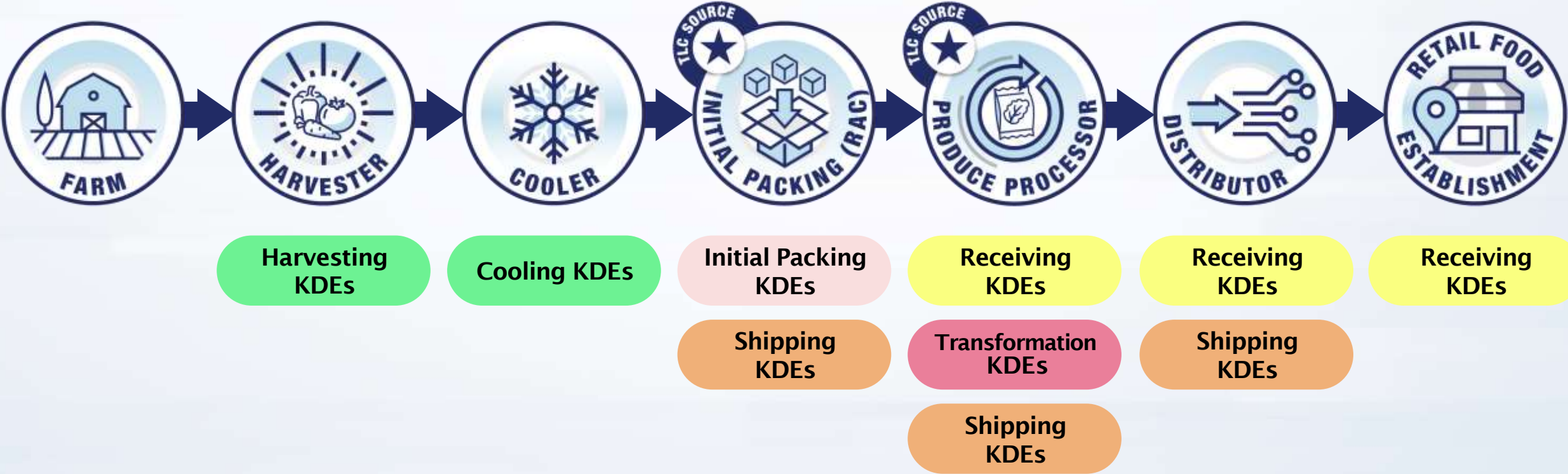


Traceability Plan

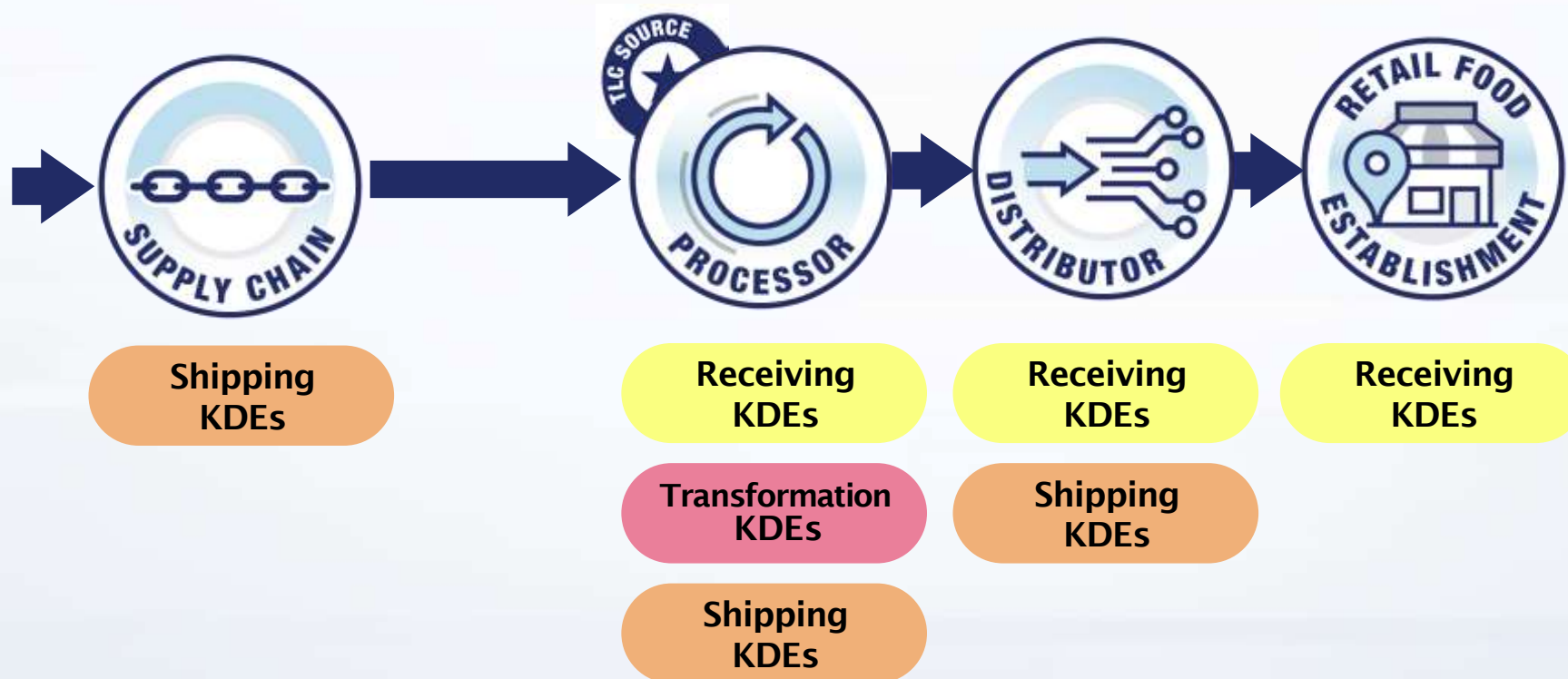


Working with supply chain partners

Supply Chain Example: Fresh Produce



Partial Supply Chain Example



Traceability Plan

Manufacturer Example



Receiving KDEs

- For each traceability lot of FTL food received, the following KDEs should be linked to the traceability lot:
- TLC*
- How much you received*
- What you received*
- Where it came from*
- Where you received it*
- Date you received it*
- Traceability Lot Code Source information*
- Reference document information



Transformation KDEs

- For each traceability lot of FTL food used as an ingredient, the following KDEs should be linked to the new traceability lot:
 - Incoming TLC*
 - How much you used
 - What you used*
- For each new traceability lot of food produced:
 - New TLC
 - Where you transformed it (i.e., the TLC Source)
 - Date you made it
 - What you made
 - How much you made
 - Reference document information



Shipping KDEs

- For each traceability lot of FTL food you ship, the following KDEs should be linked to the traceability lot:
- TLC
- How much you shipped
- What you shipped
- Where you shipped it
- Where you shipped it from
- Date you shipped it
- Traceability lot code source information
- Reference document information

* indicates KDEs you receive

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners specific information (key data elements or KDEs) for certain critical tracking events (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

Graphics on the subsequent pages provide readers with a list of KDEs required for each CTE performed.



Records Maintenance and Availability



Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



Records must be **kept for 2 years**.



Available **within 24 hours (or reasonable time if FDA agrees)**. May be stored **offsite or by another entity**.



During an outbreak - **electronic sortable spreadsheet** within 24 hours of a request (including a **phone request**).

Electronic Sortable Spreadsheet

- Upon request by FDA, firms must provide an electronic sortable spreadsheet containing the information you are required to maintain:
 - When necessary to help prevent or mitigate a foodborne illness outbreak;
 - Assist in the implementation of a recall;
 - Or otherwise address a threat to public health
- Must be made available to FDA within 24 hours or within a reasonable, agreed upon time
- The electronic sortable spreadsheet will assist FDA in analyzing traceability information quickly

Electronic Sortable Spreadsheet Example

This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403.BIUB:12OCT2020	50 CASES	CHARLES CHEESE CO. BRAND FETA CHEESE 10 x 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	FFRN:456456	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, TLCville , MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	https://id.gs1.org/01/11411411411402/10/FPP16-092420	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	https://id.gs1.org/01/11411411411401/10/FPP16-092120	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	FreshFish BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	FreshFish Importer Inc.	Distro Foodservice DC #45	9/22/2020	https://id.gs1.org/01/22322322322302/10/FFI2020-09-20	BOL 22302

*See Master Data Spreadsheet for full location descriptions

Compliance date

January 20, 2026

- Applies to all firms
- Provides 3 years for covered entities to work with supply chain
- We will educate before and while we regulate

More to come

- Outreach, education, technical assistance
- Additional communications materials
- Development of system for sending required information to FDA



Implementation and Enforcement



- Currently considering best approach for conducting inspections under this rule
- Developing compliance strategy and plan to work with State, Local, Tribal, Territorial and other regulatory partners to enforce rule

What can industry do to get started?

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any exemptions apply](#) to your situation?
3. What [Critical Tracking Events \(CTEs\)](#) do you conduct?
4. What [Key Data Elements \(KDEs\)](#) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the final rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners.
 - Understand the record keeping practices in your supply chains
 - Determine how best to communicate required information
 - Discuss potential solutions
7. More resources available [here](#).



Available Resources

- **Food Traceability Final Rule ([Federal Register](#))**
 - Link directly to codified (Bookmark this!): <https://www.federalregister.gov/d/2022-24417/p-amd-1>
 - CTRL + F
- **Food Traceability Final Rule [webpage](#)**
 - NEW translations!
- **Frequently Asked Questions ([FAQs](#))**
 - NEW search feature!
- **Food Traceability Final Rule [Webinar](#)**
- **Critical Tracking Events and Key Data Elements [document](#)**
- **Exemptions [tool](#)**
- **Food Traceability List [webpage](#)**
- **Risk Ranking Model Results [tool](#)**

Available Resources (cont.)

- **Supply Chain Examples:**

- Produce Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Seafood Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Cheese Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)

Retail Food Establishments and Restaurants

- Retail Food Establishments (RFEs) and Restaurants: [What Records Do I Need to Keep for the Food Traceability Rule?](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About the Food Traceability Rule](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About Establishing and Maintaining a Traceability Plan for the Food Traceability Rule](#)

Questions?

- FSMA Technical Assistance Network (TAN): <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

Thank you!



Food Safety Summit 2023

Looking forward and back: How companies can establish a robust and compliant traceability program

Traceability *A Nestlé Perspective*

David Clifford
Director, Food Safety Nestlé USA

May 2023



A Shakespearean comedy?

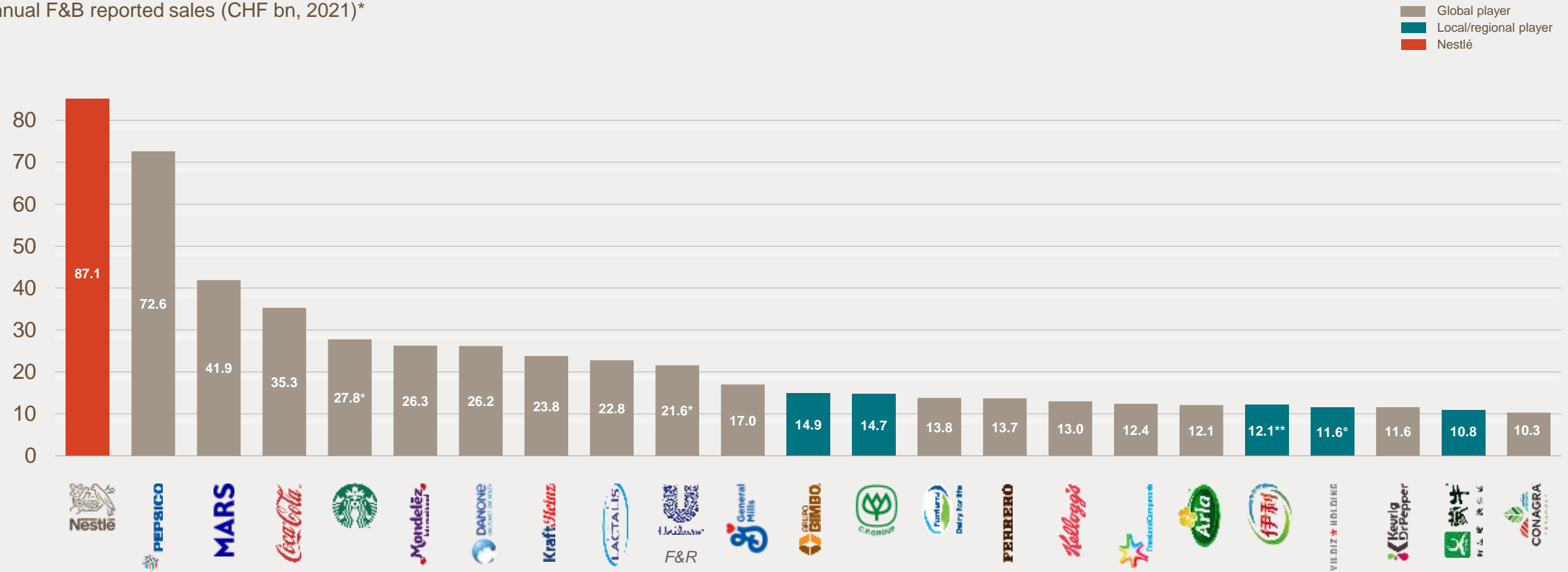
Is this thing we seek worth the cost



Nestle is leading in a highly competitive market

The CHF>10bn Food and Beverages companies 2021

Annual F&B reported sales (CHF bn, 2021)*



■ Global player
■ Local/regional player
■ Nestlé

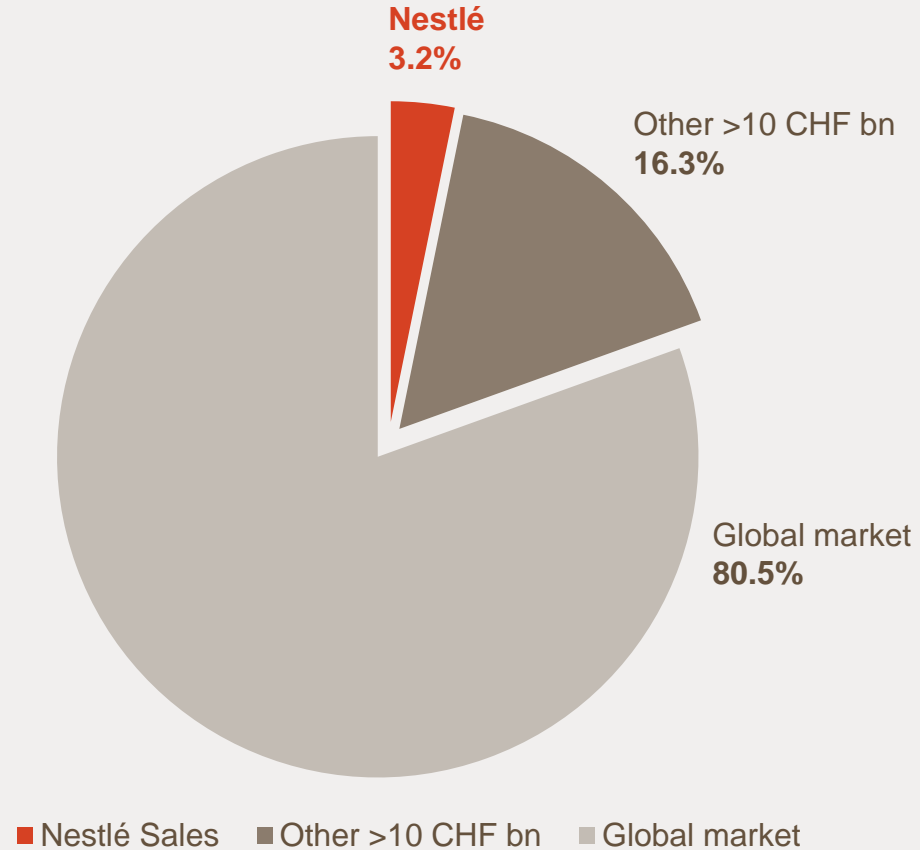
NB: Mars & Lactalis figures are estimates. Unilever figure is F&B sales only
 * Computed with last 4 quarters available (different fiscal year) / ** 9M 21 / ° 2016 result

Nestlé US brands are in 97% of households



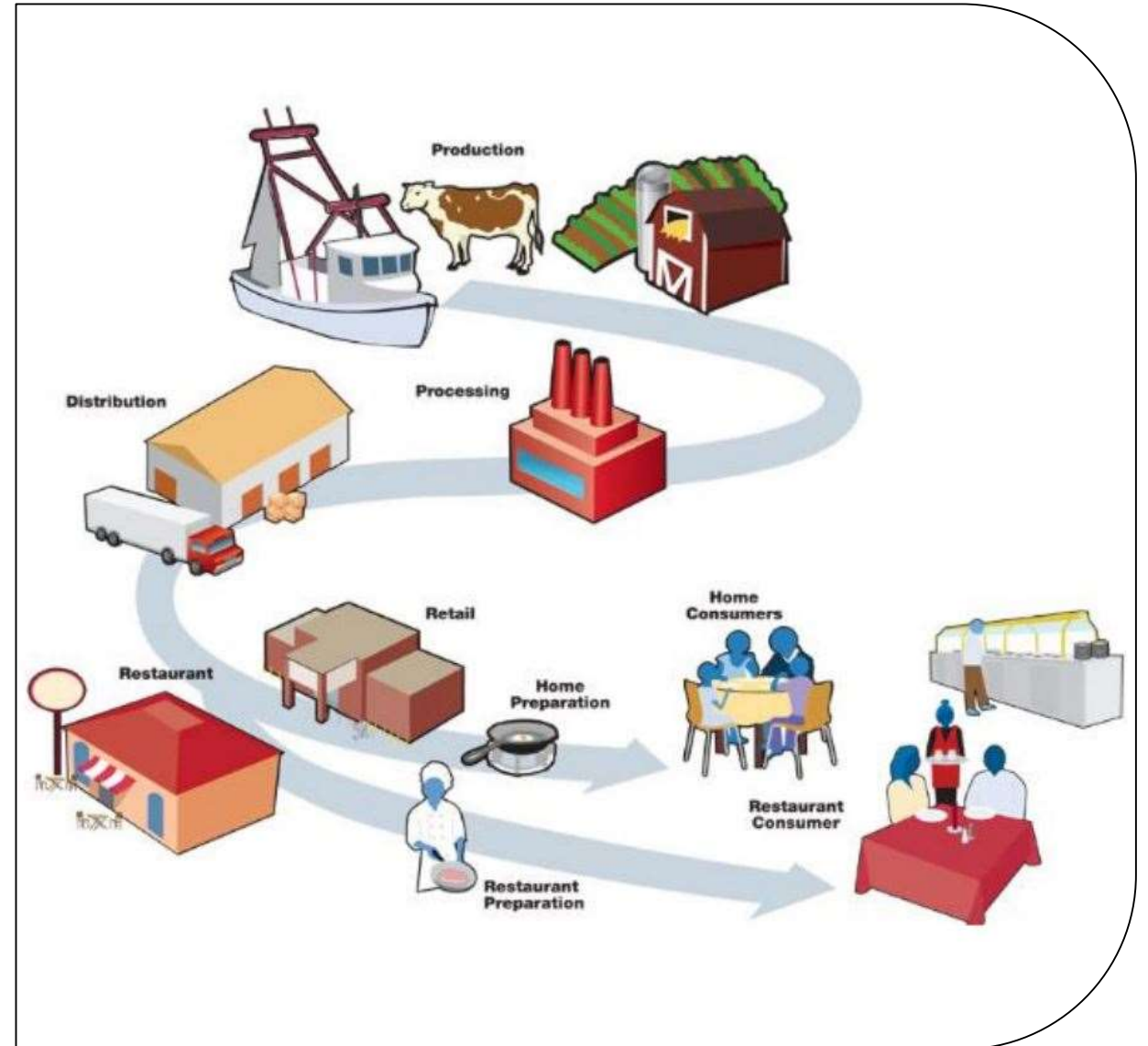
... but with only 3.2%* of global market

*Based on Euromonitor data including Hot Beverages (\$162bn), Soft Drinks (\$593bn) and Packaged Food (\$2589bn) categories



Food Supply Chain

We aim to have true farm to fork traceability, but the reality is...we achieve one up and one down....



Supply Chain Preventive Control / Vendor Management Program



Nestlé North America	
Raw Materials	3,515
Vendor Sites	833
High Risk	661
Low Risk	172

Nestlé Global	
Raw Materials	26,408
Vendor Sites	7,416
High Risk	4,199
Low Risk	3,217



High Risk – Vendor controls the significant hazard
Low Risk – Nestlé controls the significant hazard



In addition to GFSI, qualification includes detailed assessment which is linked to raw material intrinsic risk + Nestlé factory usage



Annual verification maintained through GFSI as well as remote and/or on-site assessments as required through local risk assessment



Vendor performance / Partnership – Performance drives verification activities and frequency of assessments



Traceability enabled by Technology

Supplier are our partners in leveraging technology as an aid to improve food safety, quality consistency and transparency...

- SAP used in combination with other digital systems
- Nestlé IS/IT infrastructure enables global view
- Vendor batch code, material number and Nestlé batch codes used to trace
- Data transferred from manufacturing to Nestlé DC's and WH's
- Currently no electronic data transfer to customers



Traceability in SAP/Nestle

Material receipt and storage

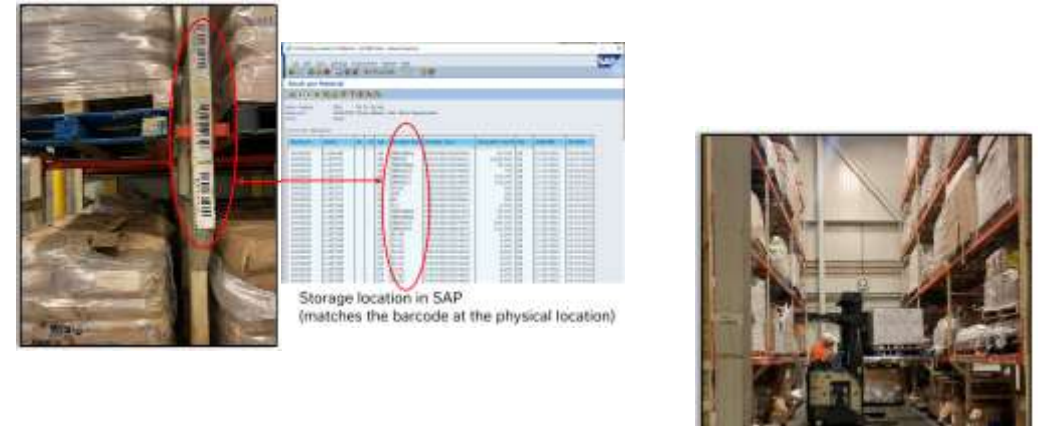
1



Material arrives at receiving dock with a vendor tag

New pallet tag created/placed on material. Material assigned Nestle batch code based on vendor manu date and PO

2



Inspection plan created. QA evaluates material for release and usage disposition

Material transferred to storage location

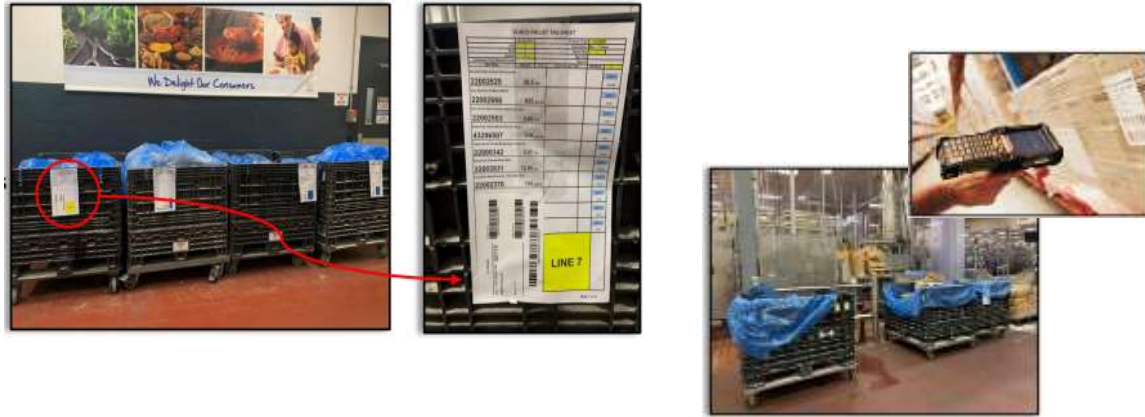
- ✓ Certificate of Analysis
- ✓ Bill of Lading
- ✓ Nestlé receipt check sheet

- ✓ Every physical storage location is barcoded
- ✓ As material travels throughout factory new location/usage reflected in SAP

Traceability in SAP/Nestle

Material usage and finished product

3



During production material is scanned from WH location and transported to line

Material is consumed (barcode scanned) at time of use

4



Finished Product is packaged into cases/palletized.

Product picked to fulfill customer orders.

- ✓ Minor ingredients may be handled at central location
- ✓ Individual ingredients combined into a mixed pallet
- ✓ Mixed pallet receives a new pallet tag
- ✓ Mixed pallet brought to line; scanned into use

- ✓ All finished products given a new independent pallet tag
- ✓ All shipments are tracked in SAP

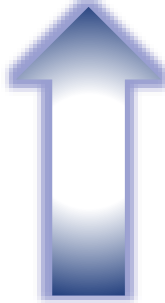
Traceability in SAP/Nestle

SAP enables visibility for usage analysis

Display Batch Where-Used List

Bottom-Up Analysis

Material	Material Short Text	Batch	Plant	Ship-to party	Ship-To Name
22001316	Potato Diced 3/8in IQF 1400b	0320	5959		
22001316	Potato Diced 3/8in IQF 1400b	0320	5959		
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5959		
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5070		
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5070	1068451	US DC DHL 5702
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702		
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1092782	Stewarts Ice Cream
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1068667	NESTLE DC SPRINGVILLE, UT
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5070		
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1092169	Burns Foods
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1104886	McLane Midwest - MI
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1879099	Wegmans Food Markets Inc
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1093384	Kroger
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1088547	Mejer DC 89
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1088469	Mejer
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1091636	Hannaford Bros
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	5251561	Kroger Cincinnati Fresh
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1091116	Delhaize DC 1
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1094531	Mejer Inc Df 805
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1089469	Mejer
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	4129960	Giant Eagle Inc
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	4129960	Giant Eagle Inc
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1089447	SpartanNash Omaha
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1088165	Hemmens Vend 0361
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	5065649	McLane Ohio - MG
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1091627	McLane Northeast
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	4462348	Mejer Df 872
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1097395	McLane Northeast Concord
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	6317923	SpartanNash Severn
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	2493524	McLane Pennsylvania - PA
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5702	1088922	SpartanNash Saint Cloud



Display Batch Where-Used List

Top-Down Analysis

Material	Material Short Text	Batch	Plant
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5959
12048860	STOUFFER'S Meatloaf 12x16oz US	1048595911	5959
44055328	Carton Bd STFR Meatloaf 29flozUS 5/20	1009	5959
44055328	Carton Bd STFR Meatloaf 29flozUS 5/20	1009	5959
44055328	Carton Bd STFR Meatloaf 29flozUS 5/20	1009	5959
44055328	Carton Bd STFR Meatloaf 29flozUS 5/20	1009	5959
44049483	Tray PET Oval STFR 60/40 29flozUS 4/20	0279	5959
44049483	Tray PET Oval STFR 60/40 29flozUS 4/20	0279	5959
44049483	Tray PET Oval STFR 60/40 29flozUS 4/20	0279	5959
44049483	Tray PET Oval STFR 60/40 29flozUS 4/20	0279	5959
44040636	Beef Broth Chld Pal MP182-23 35b US	1034	5959
44040636	Beef Broth Chld Pal MP182-23 35b US	1034	5959
44040636	Beef Broth Chld Pal MP182-23 35b US	10345489	5440
44040636	Beef Broth Chld Pal MP182-23 35b US	10345489	5440
44040636	Beef Broth Chld Pal MP182-23 35b US	10345489	5489
44040636	Beef Broth Chld Pal MP182-23 35b US	10345489	5489
22027815	Final Blend Beef Broth 791820	1034FB203A	5489
22027815	Final Blend Beef Broth 791820	1034FB203A	5489
22027613	Liquid Mcted Beef Bone Fat 773811	10345489	5489
22027613	Liquid Mcted Beef Bone Fat 773811	10345489	5489
22001238	Fat Beef Bone 50b	0364K1005	5489
22001238	Fat Beef Bone 50b	0364K1005	5489
22027608	Liquid Beef Sauce Blend 773500	10345489	5489
22027608	Liquid Beef Sauce Blend 773500	10345489	5489
22002342	Beef Stock 38-40% Solids Frozen	0095N1013A	5489
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5489
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5489
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5440
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5440
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5489
22002342	Beef Stock 38-40% Solids Frozen	0095N1013	5440
22002342	Beef Stock 38-40% Solids Frozen	0095L0272K	5489
22002342	Beef Stock 38-40% Solids Frozen	0095L0272	5489
22002342	Beef Stock 38-40% Solids Frozen	0095L0272	5489
22002342	Beef Stock 38-40% Solids Frozen	0095L0272	5440

Bottom-Up Analysis

When a RM batch is entered this transaction will display:

- the FG the material was consumed in
- where the FG was shipped

Top-Down Analysis

When a FG batch is entered this transaction will display:

- Each RM and batch information that was consumed into the recipe/batch



Quality

Traceability in SAP/Nestle

SAP...awesome yet not a complete solution itself

- Poor quality and inconsistent data from vendors
 - We generate our own...
 - No vendor ERP
 - Brokers
- Contract Manufacturing (virtual factory, etc)
 - >85 locations
 - Multitude of systems/platforms
- Acquired business integration
 - 2-3yr integration path
 - Costly
 - Resource intense



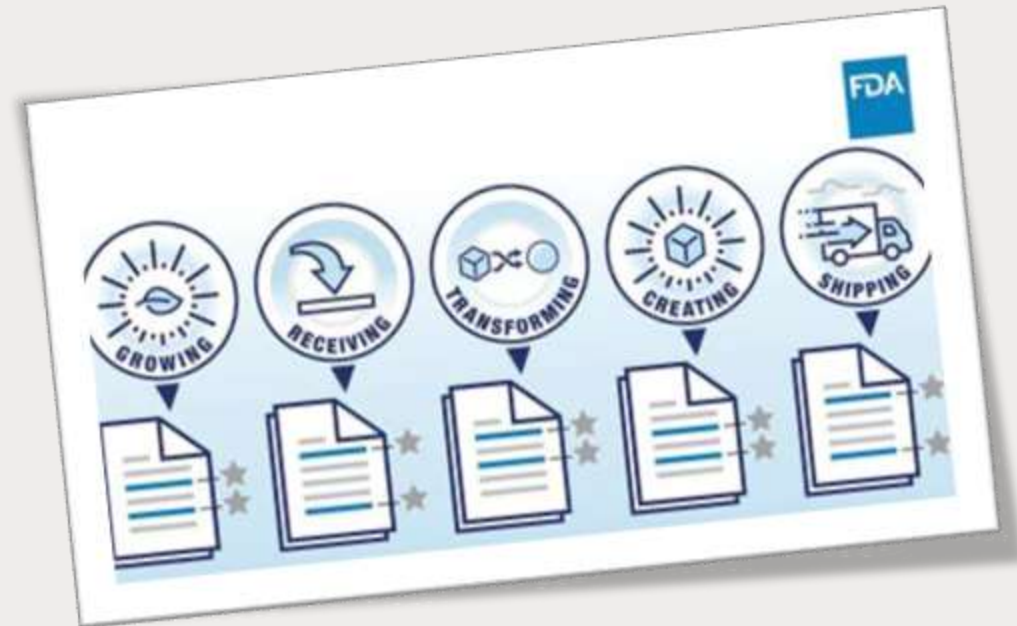
Ex.

- ⊗ 3 company names
- ⊗ 2 item numbers
- ⊗ 3 batch identifiers

US FDA Traceability final rule

What it means and impacts

- A list of 'high risk' foods subject to additional* traceability requirements
- Establishes recordkeeping requirements for 'critical tracking events' (CTEs)
- Identifies 'key data elements' (KDEs) necessary



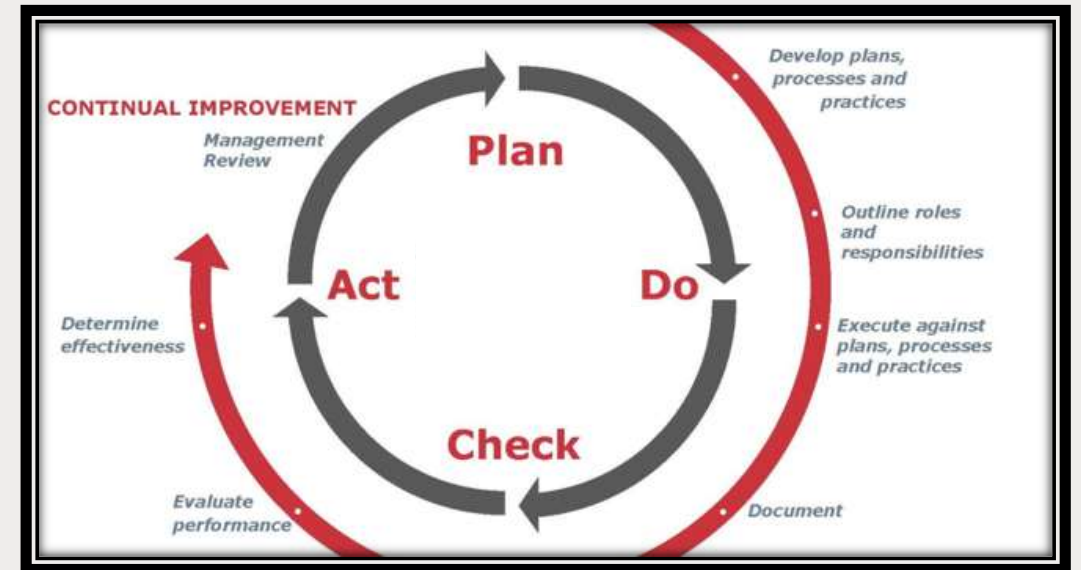
*beyond the one up/one back requirements under the Bioterrorism act

US FDA Traceability final rule

Nestlé TRACEABILITY WORKSHOP (the who what when where how)

- Understand final rule and current practices
- Internal Case Studies to explore gaps
- Action register for compliance
 - On site at pilot factory
 - 1.5days (half day process walk through; full day gap assessment)
- STAKEHOLDERS – Legal (internal and external support), Regulatory, Quality and Food Safety Mgmt, Digital, Crisis Mgmt, QM Vendor Mgmt, Supply Chain/Logistics, Applications Group (Product Development), InterMarket Supply, Commercial Planning

Review of Final Rule	1.5hr	Legal team
Overview current practices	1hr	Factory (2) QM
Case Studies	3.5hr	Legal team
Actions/Gaps	1hr	Corp QM



US FDA Traceability final rule

Nestlé TRACEABILITY WORKSHOP (the who what when where how)

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Pre-Work

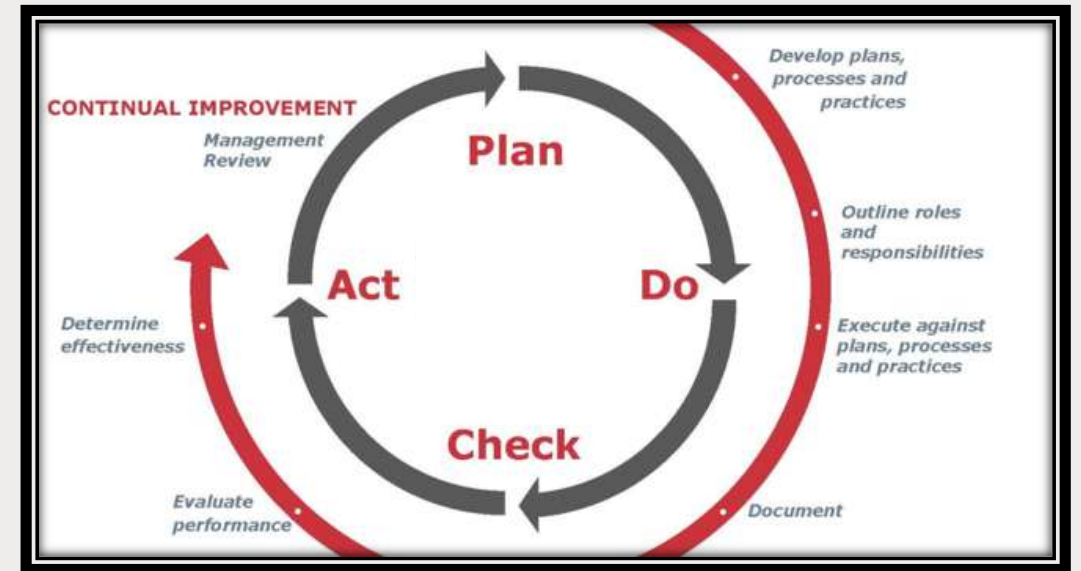
- Materials in scope of final rule
- Materials in scope of workshop/case study
 - ➔ Breaded/Frozen not fully cooked fish material
 - ➔ Cut/Fresh/Chilled Onion

[Link: FDA Food Exemption Tool](#)

Material	Material description	Material Group	Material Group Desc.	Vendor Site
43541278	Pollock Fried Bread Mix hls Parfried Fzn	R17	Fish & Sea Food	101283312
43541274	Pollock Fried Bread Mix hls Parfried Fzn	R17	Fish & Sea Food	100922708
43789510	Pollock Formed Tortilla Crusted 76.55g	R17	Fish & Sea Food	100922708

Material	Material Group	Material Group Desc.	Vendor Site
22002416	R31	Vegetables	100986889
22002405	R31	Vegetables	100986889
22002412	R31	Vegetables	100986889
22000339	R31	Vegetables	100986889
22002646	R31	Vegetables	100986889
22002406	R31	Vegetables	100986889
22000515	R31	Vegetables	100352218
22001336	R31	Vegetables	100001843
22002415	R31	Vegetables	100986889
22002418	R31	Vegetables	100986889
22002417	R31	Vegetables	100986889
22000514	R31	Vegetables	100352218
22000975	R31	Vegetables	100001843
22000975	R31	Vegetables	101015089
44196839	R31	Vegetables	100986889

- Supportive data/information
 - ➔ BOL
 - ➔ Inspection plan criteria
 - ➔ COA
 - ➔ SAP transactions
 - ➔ Vendor information
 - ➔ Shipping records (FG)



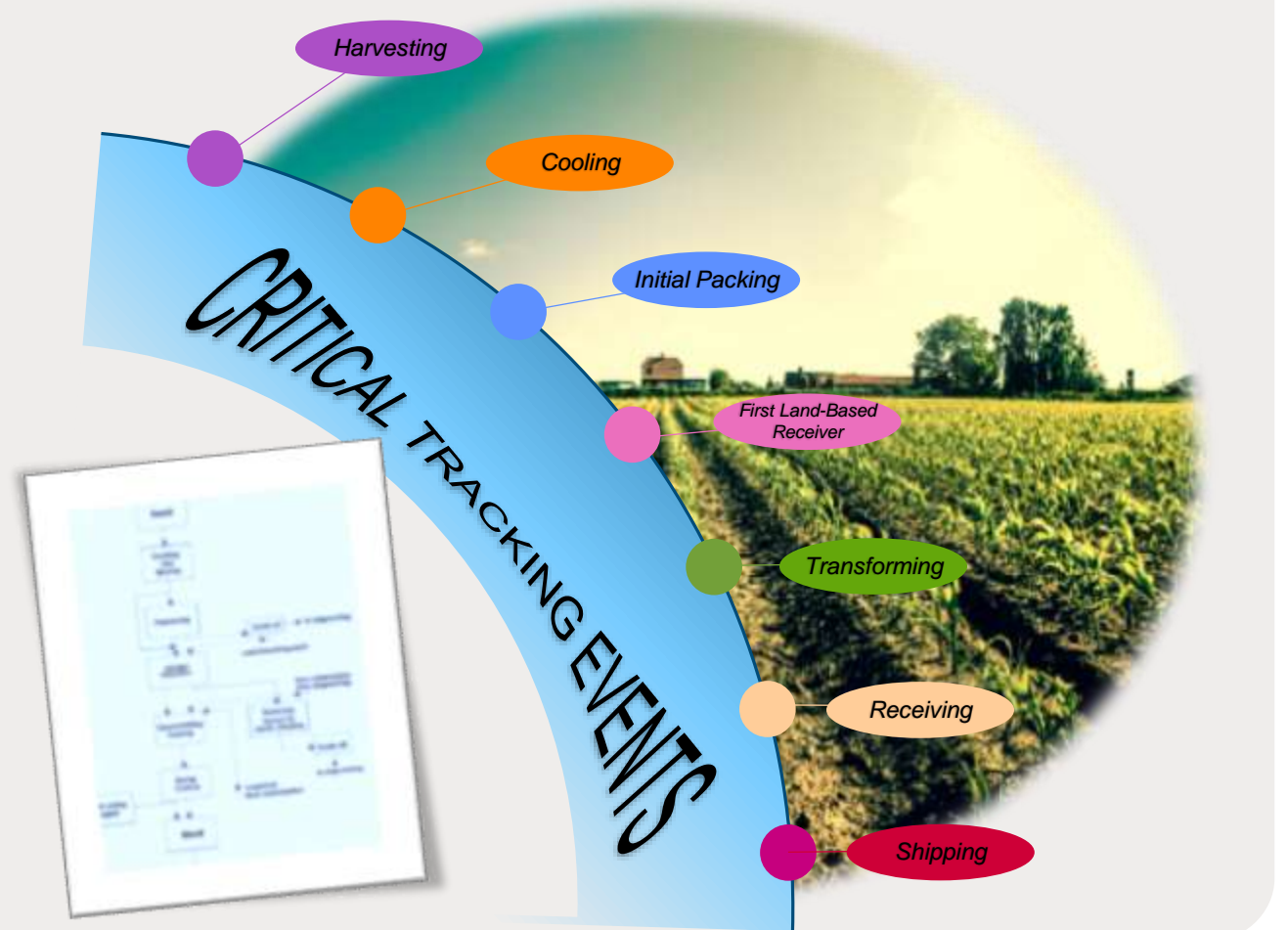
US FDA Traceability final rule

Nestlé TRACEABILITY WORKSHOP (the who what when where how)

- Understand final rule and current practices
- Internal Case Studies to explore gaps
- Action register for compliance

Workshop details

- Case Study and Gap assessment
 1. Identify Critical Tracking Events
 2. Analyze records/transactions vs final rule requirements
- Supportive data/information
 - Material flows (intermediary movement)
 - Material lot code definition
 - Process flows
 - Unit operations definitions
 - Procedural (SAP) transactions
 - Finished Goods formation/coding
 - What defines a 'lot' or 'batch'
 - Shipping records (intermediary movement)



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When compared to requirements:

- Is the information available today?
- What form (written/digital)?
- Where is that information found/stored?
- Ease of accessibility?
- Ease to assemble or collate in 24hrs?
- If digital, backup routine?



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2. Analyze records/transactions vs final rule requirements
3. Identify gaps in information
4. Consider digital solutions...



- To resolve-
 - Immediate previous source
 - Traceability lot code source reference
 - Internal Traceability Plan Policy/Standard
 - Structure of program/RACI
 - Sites without SAP

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 - Structure of program/RACI
 - Sites without SAP

- For further work
 - Comprehensive review of shipping activities
 - Cross-Docking activities
 - Intermediate ship points
 - Stakeholder management plan
 - Ghost kitchens (commercial team)
 - Application Groups (MOC)
 - R&D
 - Foreign Affiliates
 - Vendors
 - Procurement
 - Contract Manufacturing
 - DCs (internal and 3rd party)

Retailer Perspective on Traceability Requirements

Enhancing tracking and tracing of food and recordkeeping

Food Safety Summit

May 9, 2023

K.M. O'Donnell

Wegmans Food Markets, Inc.

Wegmans *since* 1916



55,000 Employees
110 Stores
States 8 (DC)



Care • High Standards • Make a Difference • Respect • Empower *Wegmans*

“Helping Customers Live Healthier Better Lives through Exceptional Food.”



In Addition to the Stores

- 3 Manufacturing Facilities
- 2 Distribution Campuses
- Organic Farm and Orchard
- Restaurant



What We Believe

- At Wegmans, we believe that good people, working toward a common goal, can accomplish anything they set out to do.
- In this spirit, **we set our goal to be the very best at serving the needs of our customers. Every action we take should be made with our customers in mind.**
- To our CUSTOMERS and our PEOPLE we pledge [continuous improvement](#), and we make the commitment: **“Every Day You Get Our Best”**



Customer Trust



It is all about **TRUST** and **CONFIDENCE**

- We work, each and every day, to build and maintain the trust of our customers
- Traceability is a pillar of trust



Critical Tracking Events (CTEs)

Points in the supply chain where product is moved, sold, or created

- **Harvest of a raw agricultural commodity (RAC)**
- **Cooling of a RAC**
- **Initial packing of a RAC**
- First land-based receiver of a food obtained from a fishing vessel
- **Shipping**
- **Receiving**
- **Transformation**

Current Status

- Wegmans Brand product and ingredient suppliers are certified to one of the GFSI benchmarked standards
- Follow the traceability required in the Bioterrorism regulations
- No difference in product treatment
- Products received by/at Wegmans in multiple manners

How do we receive product?

- Through our distribution facilities
- Cross Docked
- Direct Store Delivery (DSD)



Vendor Product Identification

- Wegmans require that you identify your products with UPC barcodes (also known as EAN/UPC Symbols) that can be scanned at point of sale
- Your UPC barcode symbols must include a valid Global Trade Item Number[®] (GTIN[®])

www.gs1us.org

Supply Chain/Logistics

- Supply Chain/What We Believe
 - Supply Chain Vision
 - What We Believe
- Appointment Scheduling
- Food Safety
- Data Sync & Accuracy
- New Item Setup
- EDI (Electronic Data Interchange)
- Transportation & Receiving
- Shipping Requirements
 - Shipping Requirements
 - General Merchandise Carton Markings
 - Guidelines for Case Design for Safe Handling
- Quick Response
- LTL Routing Guide
- Pallet Policy

Cross Dock/Quick Response

- Cross dock pallets are built store-ready by our Supplier
- Pallets are destined and labeled for a specific Store
- Entire pallet of one or more items (rainbow pallet) flowing through the DC and being merged in whole with an outbound truck for Store Delivery
- **No** case handling is required at the DC



Challenges

- Scope of Food Traceability List
- Systems Interoperability and Standardization
- Mixed pallets/split pallets
- Operational practices vs rule requirements
- Direct Store Deliveries (DSD)
- Kill step exemption – documentation

Food Traceability List (FTL)

Cheeses other than hard cheeses	Sprouts (fresh)
Shell Eggs (chicken)	Tomatoes (fresh)
Nut Butter	Tropical Tree Fruits (fresh)
Cucumbers (fresh)	Fruits and Vegetables (fresh-cut)
Herbs (fresh)	Finfish, including smoked finfish (fresh, refrigerated, and frozen)
Leafy Greens, including fresh-cut leafy greens (fresh)	Crustaceans (fresh and frozen)
Melons (fresh)	Mollusks, bivalve (fresh and frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)





Care • High Standards • Make a Difference • Respect • Empower *Wegmans*



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Potential Next Steps

- Review the Final Rule and resources

Interdepartmental team including Leadership, IT, Supply chain, Logistics, Regulatory, FSQA

- Assess Current Operations and records

Inventory management systems

- Engage Suppliers and others in the Supply Chain

Evaluate records captured, can they be shared?

- Determine gaps in current system and rule requirements

- Create a Traceability Plan

- Implement plan and capture records

Thank You

Traceability programs – where to start?

Resources and discussion

Tim Jackson, Ph.D.

Senior Science Advisor – FDA

Mahipal Kunduru, Ph.D.

Vice President, Quality – Topco

2023 Food Safety Summit – Chicago IL – May 8-11, 2023

FDA's New Era of Food Safety



Technology-Enabled Traceability

1. Develop Foundational Components
2. Encourage and Incentivize Industry Adoption of New Technologies
3. Leveraging the Digital Transformation

People-led, FSMA-based, Technology-enabled.

Core Element 1

Objectives



Tech-Enabled Traceability

- Advance food traceability fundamentals as FDA transitions from a proposed to **final Food Traceability Rule**, as required by FSMA Section 204.
- Work with international regulatory partners to create a common **global, harmonized food traceability language** based on **harmonized data elements and standards**.
- Champion **Low- or No-Cost Food Traceability** to incentivize development of tech-enabled solutions for food producers of all sizes.
- Develop and pilot **prototype to allow FDA to receive traceability data** in digital form that can be used to create outbreak investigation diagrams and improve outbreak response.

Meet the Winners of FDA's Low- or No-Cost Food Traceability Challenge

Subscribe to Email Updates

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The Traceability Challenge Winners

A video introduced by [Deputy FDA Commissioner Frank Yiannas](#) showcases the challenge winners. And in [FDA's Low- or No-Cost Tech-Enabled Traceability Challenge Webinar](#), the teams present their solutions and respond to questions.

- Low- or No-Cost Tech-Enabled traceability challenge
- Launched June 1, 2021
- 90 submissions from 14 countries
- 12 winners announced Sep 2021
- Teams from US Canada New Zealand
- Solutions include:
 - Downloadable software,
 - Mobile apps,
 - Block chain technologies
 - Open data networks,
 - IoT technologies,
 - Machine learning



Global Food Traceability Center



What is Traceability?

Traceability is the ability to track a product through its supply chain including its creation, transformation(s), depletion, and locations.



Why Traceability?

Traceability has many use cases including food safety, fraud prevention, supply chain management efficiency, ESG initiatives.



How to Implement

Make your own traceability plan, get sector specific guidance, and more with GFTC's tools, training, and customized services

Implementing a traceability program

- Map current state
 - Inventory of raw materials, suppliers and supplier facilities
 - Products and manufacturing facilities
 - Customers or downstream receivers
- Determine objectives of program and available resources
- Map process and determine critical tracking events (CTE) and key data elements at each step (KDE)
- Determine gaps in internal and partner systems
- Select solution for data management and communication
- Create and implement traceability plan
 - Conduct pilot (s)





The Global Language of Business

Retail Grocery and Foodservice

Application of GS1 System of Standards to Support FSMA 204

Guideline

Release 1.0, March 1, 2023



Apply unique global identifiers

- Product
- Location
- Party
- Logistic units



GTIN

Global Trade Item Number® (GTIN®) is used to uniquely identify a trade item.



SSCC

A Serial Shipping Container Code (SSCC) is a unique number to identify a logistic unit.



GLN

Global Location Number (GLN) is used to uniquely identify a location or stakeholder.



Questions?

