



Upcoming FDA Traceability Rule What Canadian Suppliers Need to Know

October 20, 2022

REPOSITRAK.COM

ReposiTrak Began as a Collaboration With Former HHS Secretary Leavitt

The goal was to address the looming changes from FSMA, including traceability







"We realized that we could not inspect our way to safer food, and that food safety would need to become focused on prevention, rather than inspection."

– Michael Leavitt, Former. Sec. of Health and Human Services under Bush and 3-time Utah Governor





The Result

The Largest
Connected
Network of
Food Suppliers
in the World

30,000+ suppliers

110,000+ facilities

100+ countries

15 million transactions processed per day\$150 million+ invested

Exclusively endorsed by industry trade associations:







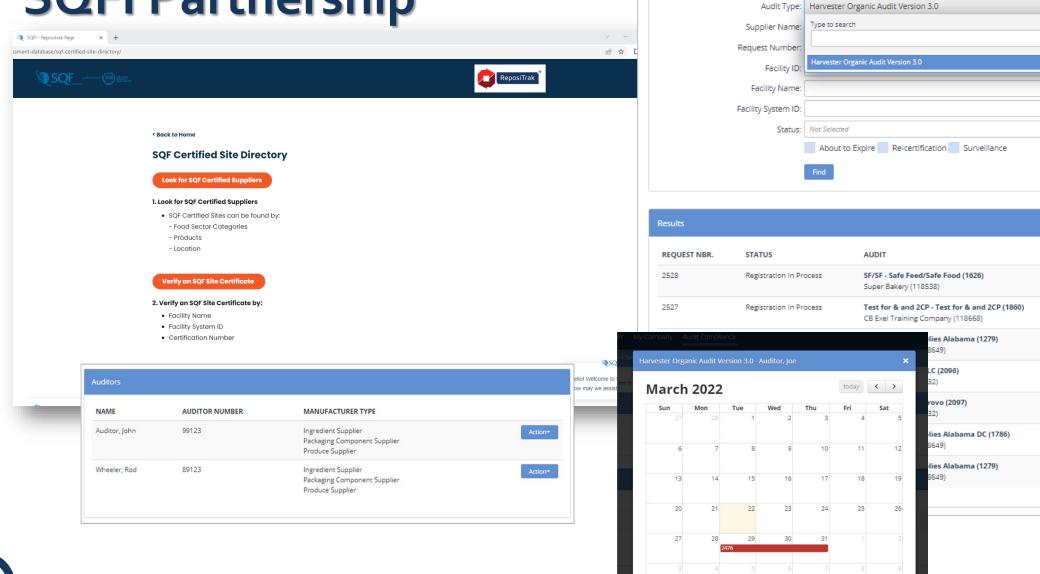








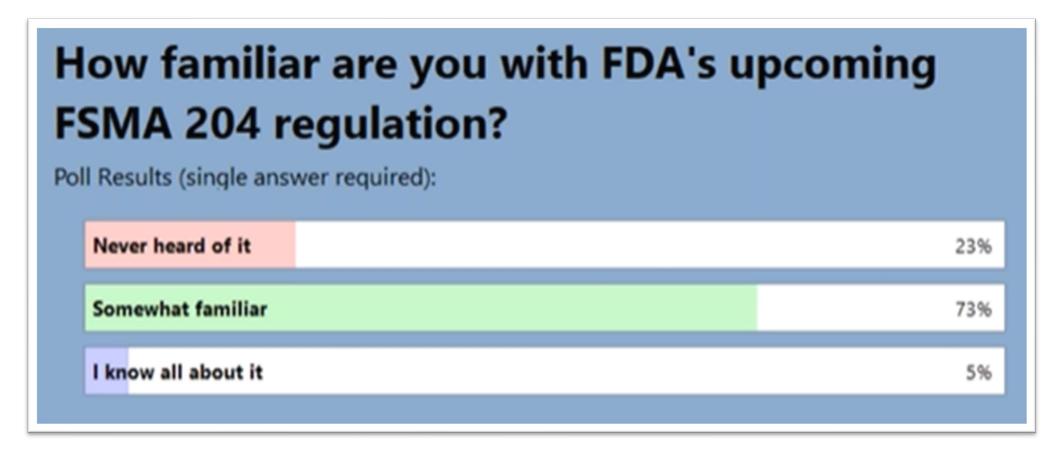
SQFI Partnership





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Traceability (Transparency)... is Inherently Good





We can all agree...if traceability were free and easy, it would be widely adopted in the industry

What is Traceability?

- Consumers value brand trust and transparency more than ever
- Faster, more precise recalls will save the industry billions while saving lives
- Better traceability leads to better preventative controls for food safety
- Valuable inventory insights improve forecasting & ordering and reduce food waste







https://www.fda.gov/media/1 39868/download







"Ultimately, we want to have end-to-end traceability throughout the food safety system."

Core Element 1: Tech-Enabled Traceability

We are advancing traceability to help protect consumers from contaminated products by doing rapid tracebacks, identifying specific sources and helping to remove products from the marketplace as quickly as possible when necessary. The first step in our work will be completing FSMA Section 204 rulemaking to harmonize the key data elements and critical tracking events needed for enhanced traceability. Establishing this foundation for traceability will allow stakeholders in the supply chain to adopt and leverage digitally-enabled technologies, enable data sharing, and introduce approaches that greatly reduce the time it takes to identify the origin of a contaminated food tied to a recall and/ or outbreak. This will also create the transparency needed to anticipate and help prevent supply chain disruptions in a public health emergency, such as a pandemic.



Ultimately, we want to have end-to-end traceability throughout the food safety system. We want to explore ways to encourage firms to

voluntarily adopt tracing technologies and ways to harmonize tracing activities, which will support interoperability across a variety of technology solutions, working towards outcomes that are achievable for all sectors.

1.1 Develop Foundational Components

- Help the food system to speak the same traceability language through the use and standardization
 of critical tracking events and key data elements.
- Strive to enable industry compliance with FDA's traceability regulation using existing consensus standards, where possible.
- Expand FDA's capacity to process data quickly for all food commodities, encouraging the expansion
 of traceability to cover the broadest range of commodities on a voluntary basis.
- Play a lead role in promoting and participating in governance and harmonization with U.S. and international regulatory counterparts through bodies such as GS1 and Codex.
- Develop ways to achieve interoperability. Specifically, work with standards bodies, technology
 providers, and users to help ensure systems are designed with interoperability as a foundational
 component.

1.2 Encourage and Incentivize Industry Adoption of New Technologies

- Demonstrate FDA's commitment to promote industry adoption by highlighting the wide-ranging benefits of tech-enabled traceability in outreach to the food industry and engaging in conversation with non-traditional stakeholders (e.g. financial industry, technology firms, insurance companies).
- Consider how to address concerns about how to disclose actions related to traceability in a way that
 provides any necessary protection of confidentiality and proprietary interests while advancing
 transparency.
- Explore ways for FDA to recognize adoption of strong traceability systems in how we approach
 our food safety oversight activities (e.g., taking traceability into account in risk-based planning for
 inspections).









KDE's Descriptors

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

www.fda.gov

Key **Concepts** of the Proposed Rule



Background

Proposed

Requirements



- 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

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

Key Data Elements

Critical Tracking Events

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.

Produced Item

Batch/Lot #

Shipper

From Location

Receiver

To Location

Received Quantity

Date Received

Purchase Order Number

Tracking Id

Entry Number

Transporter Name





The ReposiTrak **Network includes** thousands of suppliers who will be impacted by FSMA 204...and this number doesn't include companies producing products with nut butters.











3,029

Produce Companies

1,219

Dairy Companies, incl. Soft Cheeses & Shell Eggs

1,052

Seafood Companies





Proposed Food Traceability List for High Risk Foods



This represents tens of thousands of SKUs sold in stores and restaurants today.







Growing KDEs

Growing area coordinates

Creation KDEs

- Location identifier and location description of where the food was created, and the date creation was completed
- The traceability product identifier and traceability product description for the food
- The quantity and unit of measure of the food
- Reference record type(s) and reference record number(s) for records relating to creation

Transformation KDEs

- Traceability product identifier and traceability product description for the foods used in transformation
- The quantity of each traceability lot of the food used in transformation
- Location identifier and location description for where the food was transformed and the date the transformation was completed
- The new traceability product identifier and traceability product description for the food produced through transformation
- The quantity and unit of measure of the food produced through transformation (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds)
- Reference record type(s) and number(s) for records relating to transformation

Shipping KDEs

- Entry number(s) assigned to the food (if imported)
- The quantity and unit of measure of the food
- Traceability product identifier and traceability product description for the food
- Location identifier, location description, and point of contact for the traceability lot code generator
- Location identifier and description of the immediate subsequent recipient of the food (other than a transporter)
- Location identifier and location description for the location from which the food was shipped, and the date and time the food was shipped
- Reference record type(s) and reference record number(s) for documents relating to shipment
- Transporter's name who transported the food from the shipper

Receiving KDEs

- Location identifier and location description for the immediate previous source (other than a transporter) of the food
- Entry number assigned to the food (if imported)
- Location identifier and location description of where the food was received, and the date and time the food was received
- The quantity and unit of measure of the food (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds)
- Traceability product identifier and traceability product description for the food
- Location identifier, location description, and point of contact for the traceability lot code generator
- Reference record type(s) and reference record number(s) (e.g., "Invoice 750A," "BOL 042520 XYX") for the records relating to receipt of the food
- The name of the transporter who transported the food to the receiver





For an average 15-store retailer...



117,000 KDE records per year!



The traceability challenge is greatest at the end of the supply chain – at distribution centers and at stores.

The Food Traceability Leadership Consortium (FTLC)





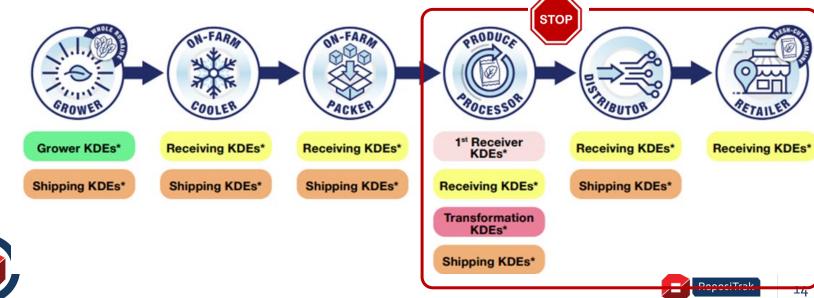






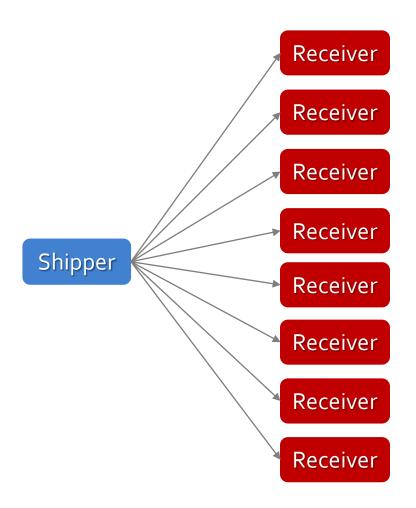


<u>Traceability STOPS here.</u> Distributors can't afford to do scanning. They have no systems to collect millions of shipment KDE records from suppliers, create and store their own KDE records and track it to DCs and down to restaurants.





From the supplier's perspective, sharing KDEs might look easy....









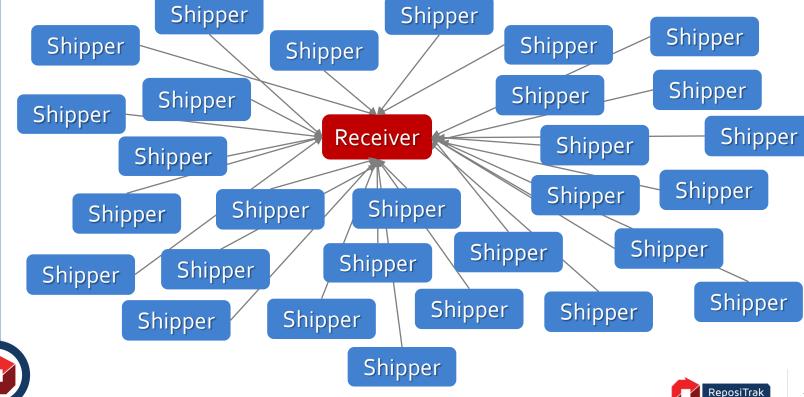


From the FTLC perspective, scanning looks economical to the Shipper, but it cripples the Receiver.

One Shipper to one Receiver, makes economic sense...



...but hundreds or thousands of Shippers to one Receiver, makes scanning economically impossible...



So, if a key issue is SCANNING a label at each Critical Tracking Event (CTE), is there any other way?

Yes, ReposiTrak has been successfully doing this at scale for years.





The distributor's challenge.
"Which truck has the FTL foods that I need to scan?
Which pallets have FTL products?"



Where would a distributor expect to find the traceability lot code in the shipper's advanced ship notice?

Ship Notice/Manifest - Pick and Pack

SHP1000227

7/9/2020 1:27:00 PM

Ship From:

Test Supplier DC Country: United States Columbus, Co 43215 Code Type: D-U-N-S Number: I

Code Type: D-U-N-S Number: Dun & Bradstreet Code: 987654

Ultimate Customer:

Test Retailer 230 West Street Columbus , OH 43212

Ship To: Test Retailer 230 West Street

Columbus, OH 43212 Code Type: Assigned by Buyer or Buyer's Agent Code: 0574893

Transaction Purpose	Ship Date	Ship Date Ship Time (F		(HHMM) Scheduled Delivery		Delivery Tin	
Original	6/4/2020						
SCAC	Routing		Bill of Lading #		Amazon Ref Num		
FEDE	FedEx Ground						

FOB						
	Payment N	fethod				
Prepaid Only						
	DO #	04#				

PO#						Store #				
S-OR	RD10117	73								
	Carton License Plate #						Carrier's Tracking #/Airbill #			
	0000000000000002509						794609048870			
	# of Units in Carton; 5									
		Line #	UPC #	EAN#	ISBN #		Description	Quantit		
		1	06758675948			1	ATHENS Desk			
			2				Vendor Item #: 1896-S1			
4 - 5 0		on Ohionod	- 4							

of Containers Shipped: 1 Gross Weight: 10 Weight UOM: Pound

Ship Notice/Manifest

General Information

Beginning Segment for Ship Notice:

Transaction Set Purpose Code : Original Shipment Identification : SHP#12345

Date: 2/25/2015 Time: 3:34:00 AM

Shipment Level Information

Carrier Details (Routing Sequence/Transit Time):

Routing Sequence Code . Origin Carrier (Air, Motor, or Ocean

Identification Code: NS

Transportation Method/Type Code: Roadrailer

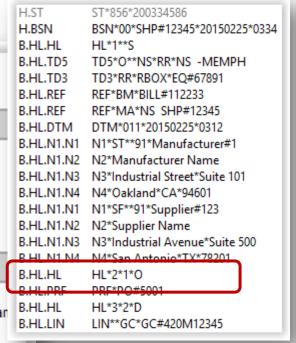
Routing: NS -MEMPH

Carrier Details (Equipment):

Equipment Description Code : Rail Car

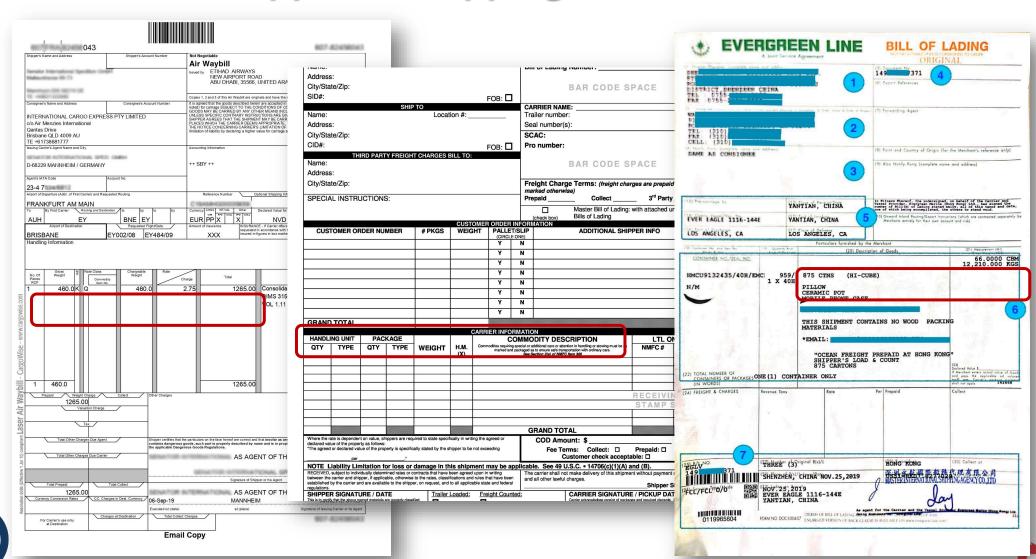
Equipment Initial: RBOX

Equipment Number: EQ#67891





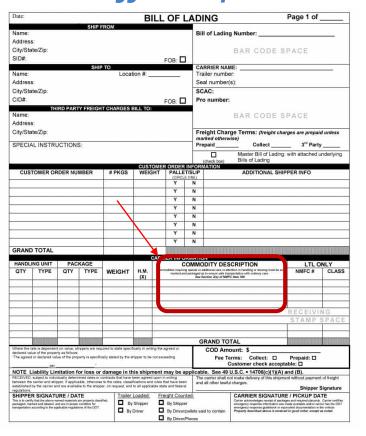
Where would a distributor expect to find the traceability lot code in the supplier's shipping document?

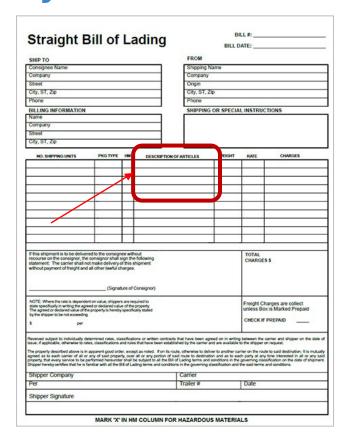


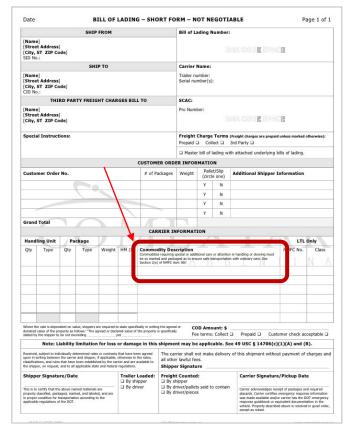


How about the DESCRIPTION of the Product?

Shown are only 3 different Bill of Lading formats where the same field is in three different places in each format











Why label scanning doesn't work.

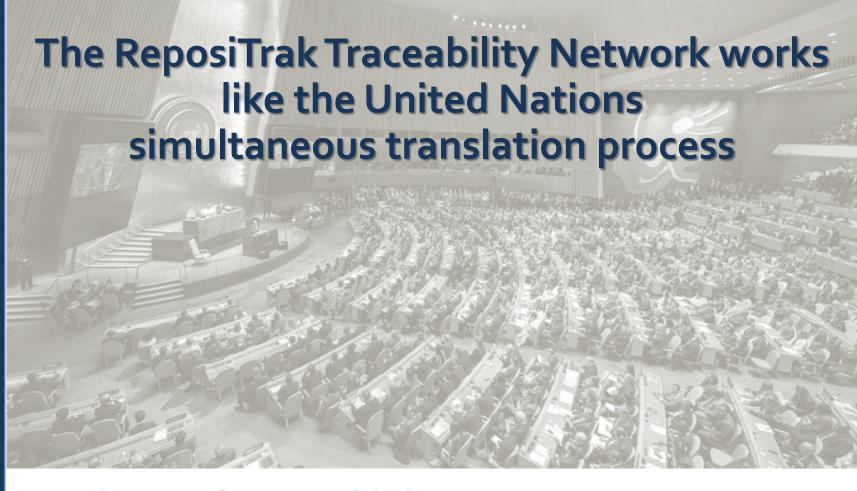
- Labor costs to scan
- Slows throughput at a distribution center or store
- Increases truck & driver wait times
- Increases hardware & software costs
- Increases DC space needed to segregate product
- Scanning and labeling would be a costly new investment for nearly all distributors and retailers
- Case level scanning would dramatically impact operating process and expense at DCs...most wholesalers average 0.005% profit margin
- Labels are likely applied before all the KDEs are known, so they don't actually carry a formatted, easily sharable KDE record



What if a system could accept data, in any format, from any system, and pass that on to any other system?

Think universal translation & exchange.

That's exactly what ReposiTrak does.



- The speaker uses his language
- The listeners hear the speech in their language



Here's how the ReposiTrak Traceability Network works

- Every supply chain participant (Shipper or Receiver) system has some system and/or electronic document that contains the KDEs.
 - SHIPPERS | records like Advanced Ship Notices, Bills of Lading, and more...
 - RECEIVERS | DC/Store systems generate Receiving records from their internal systems
- We take whatever electronic document those are, we initially register them (the format) and how they will be sent (communication protocol)
- We receive those electronic documents every time a product moves through the supply network at each CTE
- We create required records where needed, saving DC/Store Receivers/Shippers the cost, time and effort of updating their systems and processes



Advantages of the ReposiTrak Traceability Network solution?

- No standardization of documents required
 - ReposiTrak can extract KDEs from any record at any CTE
 - ReposiTrak is an OPEN system that enables input of any type; and can provide output in any format
- No special hardware/software requirements
 - ReposiTrak uses electronic document that are in use today
 - Virtually every business in food is currently sending us these same documents already
- No scanning / additional segregation of vendors/products is required at the DC
 - No changes to operational processes at DC level
- Fully interoperable.
 - Enables ePedigree of a product (geographically-based)
 - Enables analysis of all the entered data as the product moves through the supply network



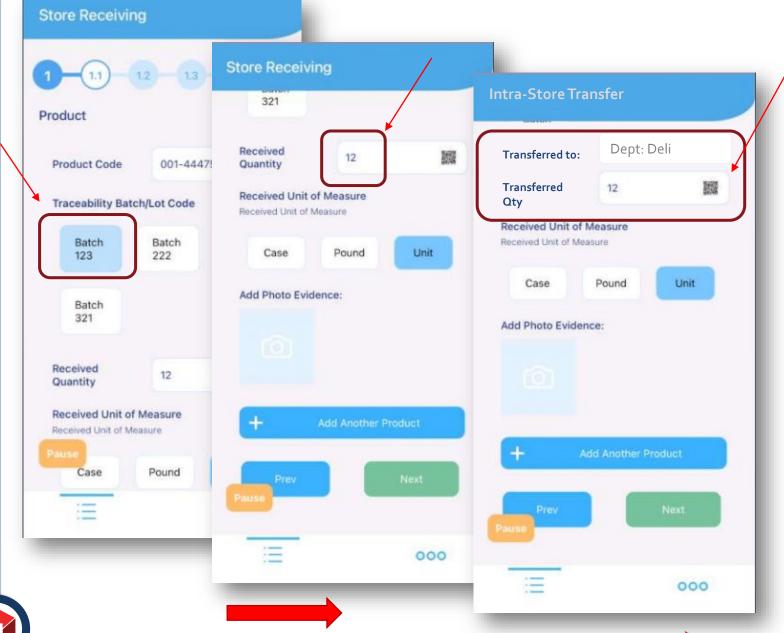


Backdoor Receiving at the Store Made Easy using a Smart Device via an App

ReposiTrak will present available Traceability Lot Codes

You choose from the list and confirm the quantity received

Need to move it to a department? Choose and transfer as a final step



The ReposiTrak Traceability Network is the industry's low cost solution

No Reason to Pass Cost to Consumer

- Easily adopted
- We already do this at scale
- We've reviewed with our trade association partners
- Caps the industry's total cost



What can you do to avoid complex and costly traceability requirements and turn it into an advantage?

- Understand that your customers are going to require you to do
 it in a way that makes it easy for them...and accept that as fact.
- Realize that the data can move independent of the product.
- Look for a solution that works with the your existing systems and traceability processes, and makes it easy for your customers.
- Avoid unproven solutions, that if they fail will expose you and your customers.
- Avoid solutions where the expense scales with your volume.
- Get moving now! Use traceability readiness as a competitive advantage to grow market share and win new customers.







Thank You