

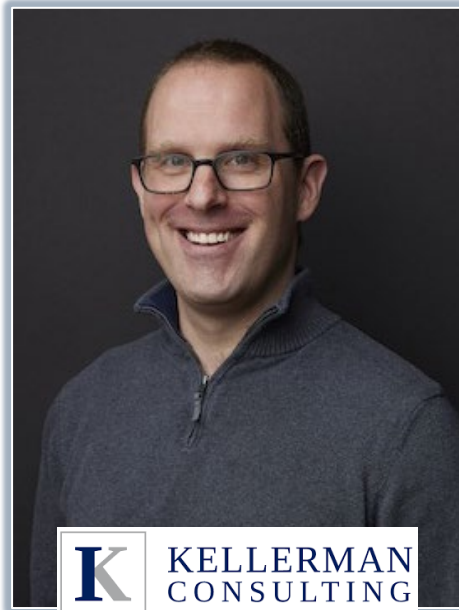


ReposiTrak

OnTrak Webinar Series

*December 2, 2021*

# Key Considerations for Recall Ready Traceability



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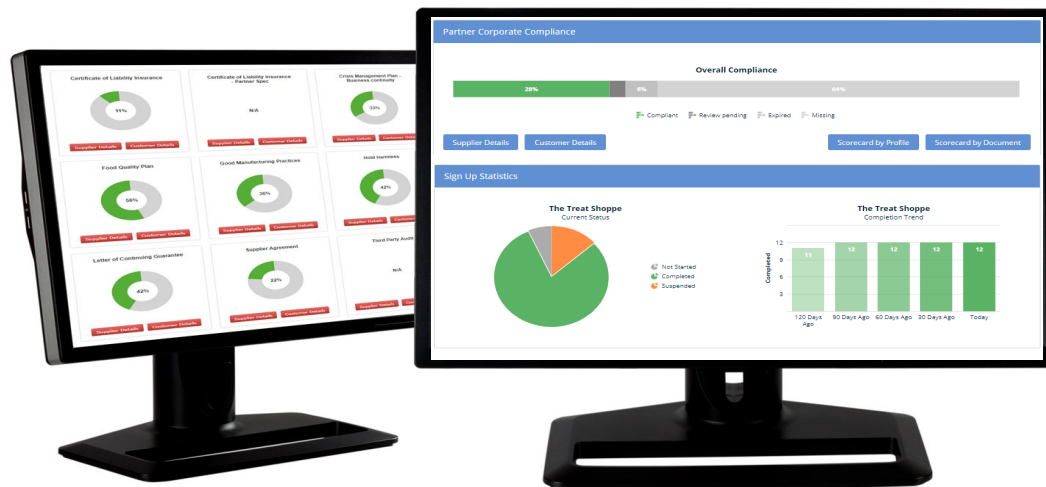
# World's Largest Network of Supply Chain Partners Sharing Documents and Data

*Improve Product Safety, Reduce Cost & Risk*

More than **100,000+**  
connections  
in the ReposiTrak network  
used in **100+** countries



Many of you and your suppliers are likely already using ReposiTrak to share documents with customers



# Exclusively Endorsed in the Industry



ReposiTrak augments our food and drug safety efforts...with a **proven, comprehensive and easy-to-implement solution** that **doesn't require systems changes** and is extremely cost effective.



We see the ReposiTrak system becoming an **industry standard** for the retail supply chain, helping all trading partners **meet the new federal food safety requirements**, reducing unsalable products and keeping the end consumer healthy.



We were looking for a technology partner to help us **raise the bar** not only with our data management and reporting, but also with upgrades to all our user interfaces. It made perfect sense to partner with ReposiTrak because of their **experience in the industry** and technical capabilities.





# We Know You're Busy, So Our Team Does the Heavy Lifting for You

## ■ Cloud-based

- Nothing to install, just use your browser

## ■ We do all the supplier follow-up for you!

- It takes up to 20 “touches” by phone, e-mail and mail on average to get and keep a supplier compliant
- We have a full-time, U.S. based, multi-lingual Customer Success Team who follow-up with your vendors to ensure adoption and compliance with your requirements

## ■ Set-up is easy

- Your supplier list and document requirements are all we need to get started



# ReposiTrak is Now the Most Complete Compliance & Quality Management Solution

World's largest document sharing network  
100,000+ locations in 100+ countries  
Customer success team handles  
supplier follow-up

Supplier  
Compliance  
Management

Automate internal forms & quality records  
Improve quality management  
Save time & money  
Reduce audit prep time

Active QMS  
Quality  
Management

COA  
Management  
Automation

Audit  
Management  
Automation

Collect COAs via email  
Track COAs to batch/lot  
Auto-validation of COAs to specs

Automate internal &  
supplier audits for  
efficiency and consistency



# Food Traceability Leadership Consortium

*Leadership in traceability*



Created a methodology



Adopted principles of an optimal solution

Minimal Cost

Easy to adopt, use and verify

Meet or exceed FDA proposed regulation



Create a Framework



Review possible solution



# Key Considerations for Recall Ready Traceability



Brian Kellerman, Co-Founder & Chief Food Safety  
Officer at Kellerman Consulting





# Kellerman Consulting

- Founded in late 2016 by Mickey and Brian Kellerman
- Mickey Kellerman has a background in industrial engineering and business operations
- Brian Kellerman has a background in Sustainable Agriculture, Teaching (Chemistry and Biology), and Safety/Quality Management (BRC)





# Kellerman Consulting Employees



**Chelsie Romberger**

- SQF Practitioner and BRC Safety Team in large corporate supply chain
- Senior Administrator in addition to quality and safety responsibilities



**Sierra Faust**

- SQF Practitioner and BRC Safety Team lead in bakeries



**Tim Grady**

- Sanitarian and Health Inspector for Licking County prior to joining Kellerman Consulting
- 3 Years of experience as a food safety consultant



**Jaime Miller**

- SQF Registered Consultant
- SQF Practitioner at Dairy Processing
- Quality Assurance at Salad Dressing Processor
- 3 Years of experience as a food safety consultant



**Phoebe Kellerman**

- LISW-S with over 12 years experience in-patient social work
- Head of Marketing



# Typical Clients

GFSI Projects

Regulatory  
Clients and GMP  
Certification

FSVP Clients

Restaurant  
HACCP

Over 550 clients in 5 years

Over 50 GFSI Projects

Over 300 FSIS, FSMA and FDA Compliant programs

Other projects include FSVP, Retail HACCP, Alternate Sanitation



## Lot Coding in Systems

- FDA and FSIS define the requirements for lot coding in Recall directives:
- Requirements focus on function during recalls to pinpoint product in the marketplace
- There is no definition for lot code format
- Common form of lot coding are:
  - Julian Coding
  - Expiration date
  - Best buy date

### **Julian Code Example:**

**22010A = 22 – Year 2022, 010 – January 10<sup>th</sup>, A = Product A**

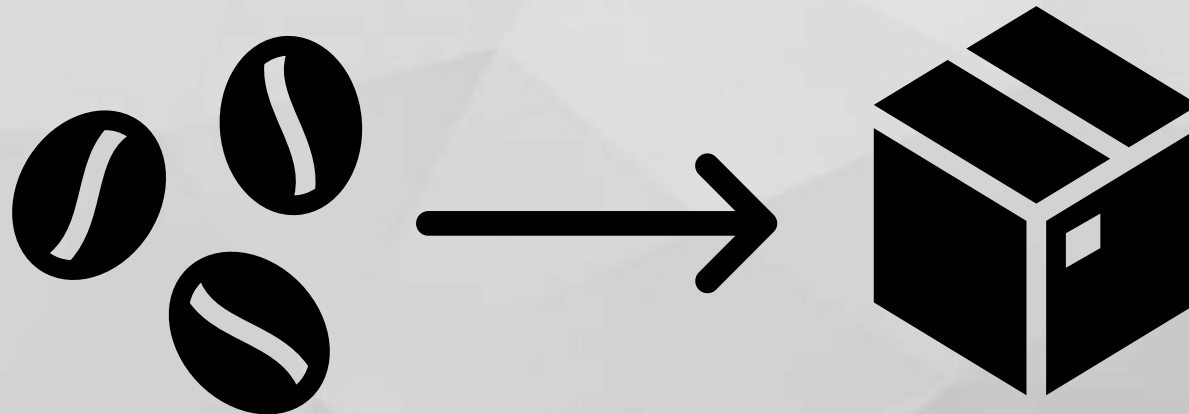
**Best Buy Example: Consume by January 10<sup>th</sup> 2023**

**Expiration Date Example: Exp. 1/10/2023**



# Mass Balance and Traceability

- Forward direction is from the receiving of a raw ingredient or raw materials forwards through the system and linked to finished product
  - Forward direction trace exercises are tests of:
    - Receiving Program,
    - inventory pulling,
    - FIFO/FEFO,
    - work-in-process manufacturing,
    - warehouse transfer and
    - production scheduling.





# Mass Balance and Traceability

- Backward direction is from a starting point of shipment of finished product back to the component ingredients
  - Backwards direction trace exercises are tests of:
    - Shipping program,
    - Finished Product rotation,
    - Final Packaging
    - Batch records,
    - Finished Product Labelling
    - 3<sup>rd</sup> Party Warehouses/Distribution Centers
    - Transportation (Company vehicles, rail or 3<sup>rd</sup> party transport)



# Traceability requirements to meet FDA or FSIS Mock Recalls



## **FDA**

- FDA does not require a mock recall in 21 CFR 7 or 21 CFR 117
- FDA inspectors have been known to request that firms perform One Mock Recall for Product, One for Packaging each year

## **FSIS**

- FSIS uses the language of Recall Simulation in addition to mock recall (see. Page 38 in FSIS-Directives 8080.1 Revision 7 (2013))
- FSIS does not mandate a number of simulations, only that they are unannounced in the facility and they are conducted to the point of contact with primary “consignees”
- *Note: GMP and GFSI Certification schemes require at least one Mock Recall and one trace exercise each year*



# FSMA Section 204 and the Food Traceability List

- For GFSI compliant programs, this will be assessed through the review of regulatory requirements
  - For soft cheese and nut butter purveyors, we can expect SQF, BRC and FSSC 22000 reviews within program
  - For Seafood purveyors we can expect SQF review within program
  - For agricultural products, we can expect PrimusGFS reviews
- Programs will need to monitor the Food Traceability list, and should include interacting with the list in mock recall scenarios
- Trainings for 2022 in facilities where products are identified as likely to be included in the FTL should be performed for the operations staff as well as administrative staff with procurement and supply chain roles



## Traceability exercise and mock recall exercises

- Kellerman Consulting produced Video Series (January/February 2022)
- Traceability exercises are accounting checks for the system
- Mock recalls include traceability functions, but serve as Crisis Tests
- Where trace exercises are performed, test is complete when forward or backwards inventory control is concluded, score is based on percentage of inventory identification
- Mock recalls include contact information, crisis decision-making, coordination of retrieved product and decisions on final disposition
  - Mock recall requires acceptable percentage of inventory retrieval, but is over when all ingredients or finished product has a determination of final handling (rework, recoup and resale, destruction)





## Final Thoughts on Trace and Mock



- Mock recalls are more important than trace exercises
- Trace ability exercises should start simple and quickly move to the hardest scenarios
- Mock recalls should increase in complexity each year
  - Add rework
  - Add recoup
  - Add 3<sup>rd</sup> party coordination
  - Select for international scenarios (where applicable)



## Case Study 1: Peanuts in Cumin 2015 at Coalescence, LLC



- On December 24<sup>th</sup> 2015, as a Quality Assurance Manager I was contacted by a supplier and informed that Spice Blend purchased for use in product included cumin found to have measurable peanut contamination.
- Recall cost \$5.7 Million, recall and subsequent legal action took 10 months
- Due to Mock recall, ERP system and diligent action, all funds were recovered through insurance claims for company



## Case Study#2: Computer illiteracy in a food factory

- A current FSMA (FDA) client had no operational record keeping.
- Incoming ingredient were lot coded from suppliers, but finished product was not lot coded
- No computer system is in place, and owner expressed reluctance to use computers
- Excel spreadsheet was created for each variety of product and had a list of all ingredients, and Julian Coding was implemented for each product on each day.
- Facility implemented a handwritten system for tracking and was successful in trace exercise in fall of 2021.
- Recommendation to add MRP/ERP system as capital becomes available



## Case Study#3: Company with MRP/ERP and no/limited ability to trace

- For a PrimusGFS project with a produce storage and distributor, two adjacent building, one incoming warehouse, a second operational building were used in the system.
- Trace was successful into the first warehouse, but produce pulled for cutting, packing and distribution into the second building was not properly tracked.
- The computer system and training was insufficient.
- Trace failed during a customer audit (United States Army) and key account was lost.
- Every piece of fruit and veg required recall of all types of that fruit and veg in the marketplace



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# Companies with No Trace Program



- Produce distributors
- Honey Processor
- Maple Syrup Processors
- Salad Dressing Spice Base (Work in Process in repurposed waste bins)
- Vertical Agriculture Facility (Lettuce and Basil)

*Facilities that have great trace systems love to show off,  
Facilities with little or no trace programs hate to talk  
about it*



## Case Study#4: Variety Packs Sold Direct to Customers over the Internet

- FDA regulated facilities with low-risk product (1 an ambient confection facility, 1 a pet treat manufacturer)
- Both facilities use lot coding is performed on all flavors at primary facilities
- All flavors of confection and pet treats are transferred to second location Pack and Distribution Center
- Lot coded products are mixed in packages without further lot coding and sent direct to customers over internet sales (Amazon and company website)
- No bar-coding system is in place, and no record keeping is used at point of variety pack build for both facilities.
- Any recall for these firm would possibly be an administrative catastrophe, even though consumers may be able to throw away product



## Case Study#5: International Dietary Supplement Success in Traceability

- Dietary Supplement capsules and liquid in plastic bottles (approximately 12 varieties), all bar coded, all shipments handled by independent Distribution Department for parent company
- Retail sales in big box retails, direct to customers over Amazon and other websites)
- International Shipments
- Preparation for SQF audit, Kellerman Consulting conducted mock recall – Kellerman Consulting selected scenario, client and parent company representatives
- 100% trace within US and 100% trace internationally

# Key Considerations for Recall Ready Traceability



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Officer at Kellerman Consulting