



# Welcome

OnTrak with FSMA: A Webinar Series

Hosted by: ReposiTrak<sup>®</sup>

# FSMA Finalizes Food Defense: How You're Expected to Prevent Intentional Adulteration



**Hilary Thesmar, PhD, RD, CFS**

VP Food Safety Programs,  
Food Marketing Institute

# FMI Antitrust Statement

**FMI believes strongly in competition.** Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

**Association meetings or workshops by their very nature bring competitors together.** It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

**Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns.** Agreements to fix prices, allocate markets, engage in product boycotts and to refuse to deal with third parties are illegal under the antitrust laws. At any association meeting discussions of prices (including elements of prices such as allowances and credit terms), quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, or selling to a particular customer, should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

**An antitrust violation does not require proof of a formal agreement.** A discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion is enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

**As a practical matter violations of these rules can have serious consequences for a company and its employees.** Antitrust investigations and litigation are lengthy, complex and disruptive. The Sherman Act is a criminal statute, and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus attorney's fees.

# FDA Authorities Already in Effect

- Increased Inspection Authority
  - Depends on appropriations
- Increased Records Access
- Mandatory Recall Authority
- Import Certification Authority
- Fees for Re-inspection
- Administration Detention
- Facility Registration and Suspension of Registration



# Review of the 7 Major Rules

Seven Major FSMA Regulations	Publication Date or Expected Date	Expected Compliance Deadline**
1. Preventive Controls – Human food	September 17, 2015	September 19, 2016
2. Preventive Controls – Animal food	September 17, 2015	September 19, 2016 cGMP September 19, 2017 PC
3. Produce Safety	November 27, 2015	November 27, 2017
4. Foreign Supplier Verification Program	November 27, 2015	May 31, 2017
5. Accreditation of Third Party Auditors	November 27, 2015	May 31, 2017
6. Sanitary Transportation	April 6, 2016	April 6, 2017
7. Food Defense	May 27, 2016	May 27, 2019

\*\* Compliance deadlines depend on several variables so check the rules for details

# FSMA Compliance at a Glance

	Produce Grower/ Farm	Manufacturing, Processing, bulk holding	Any facility who Imports (retail, wholesale, production)	Retail Distribution Center or Warehouse	Transportation: Shippers, Loaders, Carriers, Receivers
Preventive Control Plan					
Produce Safety					
Foreign Supplier Verification					
Sanitary Transportation					
Food Defense					



Impact

# FOOD DEFENSE

# Food Defense Rule Basics

- Mitigation Strategies to Protect Food Against Intentional Adulteration; Final Rule
  - Published in the *Federal Register* on May 27, 2016
  - Part 121





# Exemptions

- Very small businesses
- Holding facilities “except the holding of food in liquid storage tanks”
- Farm activities subject to the produce safety rule
- Alcoholic beverages
- Animal food

EXEMPTIONS  
EXEMPTIONS

# Food Defense Plan

- Written plans required
- Written vulnerability assessment including required explanations
- Written mitigation strategies
- Written procedures for monitoring, corrective actions and verification
- Records



# Vulnerability Assessment

- For each type of food
- Evaluate each point, step or procedure for public health impact, physical access, ability of attacker to contaminate
- Consider possibility of an inside attacker
- Results in written form regardless of the outcome



# Mitigation Strategies

- For actionable process steps, assurances are required to significantly minimize or prevent the vulnerable action from occurring.
- Written strategies and explanations required



# Management Requirements

- Monitoring – procedures, records
- Corrective actions – procedures describing the steps taken, records
- Verification – monitoring is being conducted, appropriate decisions being made, implementation of the strategies
- Review records to make sure monitoring and corrective actions are taking place
- Reanalysis of the plan every 3 years



# Records

- Food Defense Plan must be signed and dated by the owner, operator or agent in charge
  - At initiation and upon any modification
- Name, location, date, time
- Accurate and detailed to provide a history
- Maintained for 2 years
- Accessible in 24 hours (Food Defense Plan onsite)
- Food Defense Plans – 2 years after use is discontinued and must be onsite



# Records Access by FDA

- Official review and copying upon oral or written request
- Protected from public disclosure to the extent allowable under 21 CFR 20





# SUMMARY



# Key Considerations for Food Defense

- Applies to manufacturing, processing and bulk liquid holding facilities
- Written food defense plan based on vulnerability assessment
- Emphasis on records and documentation



# Food Defense: Your To-do List

Task	Retailer /Wholesaler with DC only	Manufacturer /processor or Bulk holding facility
Written Food Defense Plan		X
Vulnerability Assessment		X
Procedures and records for monitoring, corrective actions and verification		X

## Do these apply to you?

- Do you have a registered facility that manufacturers or processes food?
- Do you have a bulk liquid tank at your facility?

# Food Defense Resources

- University of Minnesota Food Protection and Defense Institute
  - <https://foodprotection.umn.edu/>
- FDA Food Defense Mitigation Strategies Database
  - <http://www.accessdata.fda.gov/scripts/fooddefensesmitigationstrategies/>

# General FSMA Resources

- **FDA Technical Assistance Network**
  - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- **FDA FSMA Email updates**
  - [https://public.govdelivery.com/accounts/USFDA/subscribe/new?topic\\_id=USFDA\\_206](https://public.govdelivery.com/accounts/USFDA/subscribe/new?topic_id=USFDA_206)
- **ReposiTrak**
  - <http://repositrak.com/>

# Thank You!

- **Interest in food safety**
  - Compliance with FSMA requirements
  - Preventive risk management
- **ReposiTrak supporting SQF user experience**
  - Easier registration
  - Faster audit results
- **Have asked ReposiTrak to go deeper into food safety**
  - Food Safety Plan management
  - Quality assurance



# Industry Standard Food Safety Platform



ReposiTrak

*Trusted Brand Protection*

## Co-founders



## Two Components



**Compliance  
Management**

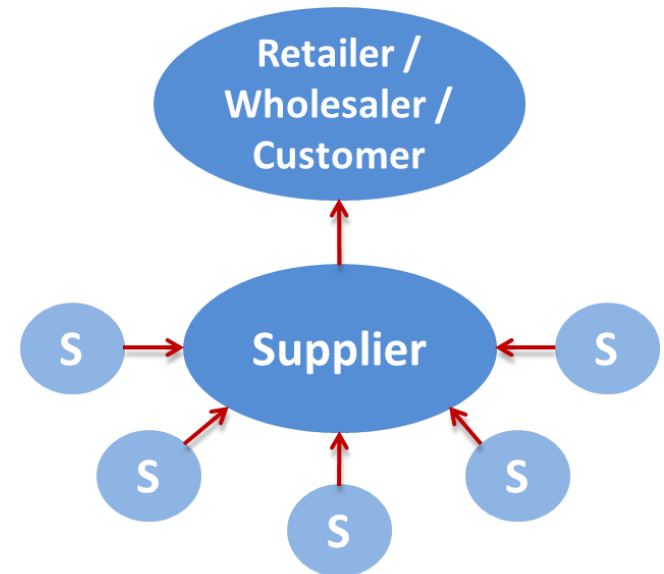


**Track & Trace**



# 1-Stop System for All Compliance Records

- Supplier & corporate records
- Dashboards and automated, proactive exception-based alerts
- Incredibly flexible
  - Choose/create supplier classifications
  - Customize document requirements
- A rapidly growing community



*For your entire supply chain*



# Our Active Approach? A Dedicated Team



- We provide a dedicated staff
- We clean AND build your supplier contact list
- We ACTIVELY follow up with suppliers to correct non-compliance

70%

**Average decline in  
Non-Compliance  
among new users  
on ReposiTrak**

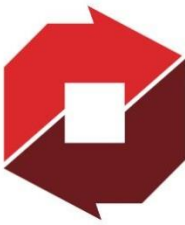
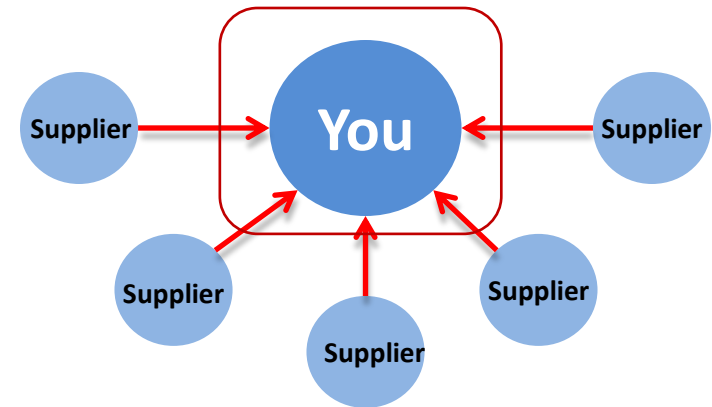




# Utilizing ReposiTrak is as Easy as 1 – 2 – 3

## Three main activities in ReposiTrak

- 1) Invite suppliers to enroll in ReposiTrak
- 2) Manage enrollment and monitor overall compliance stats
- 3) Make decisions regarding non-compliance issues



# Invite Vendor Prospects to Enroll in ReposiTrak

Enter **FOUR** pieces of information:

Company Name:	<input type="text" value="My New Vendor"/>
Contact First Name:	<input type="text" value="Sally"/>
Contact Last Name:	<input type="text" value="Smart"/>
Contact Email Address:	<input type="text" value="ssmart@mynewvendor.com"/>

Then send an invitation:

My New Vendor Smart Sally	ssmart@mynewvendor.com	Focus Group - Demo RT Customer	New	Action
Okie Oatmeal Cookies Brown N	nbrown@prescient.com 4356452552	Focus Group - Demo RT Customer		
Vendor A Chesney Ammon	achesney@parkcitygroup.com	Focus Group - Demo RT Customer		
Vendor B Sternner Josh	jsterner@parkcitygroup.com	Focus Group - Demo RT Customer		

**Manage/Update**

- Update Prospect
- Create Proxy Supplier

**Email**

- Send Invitation

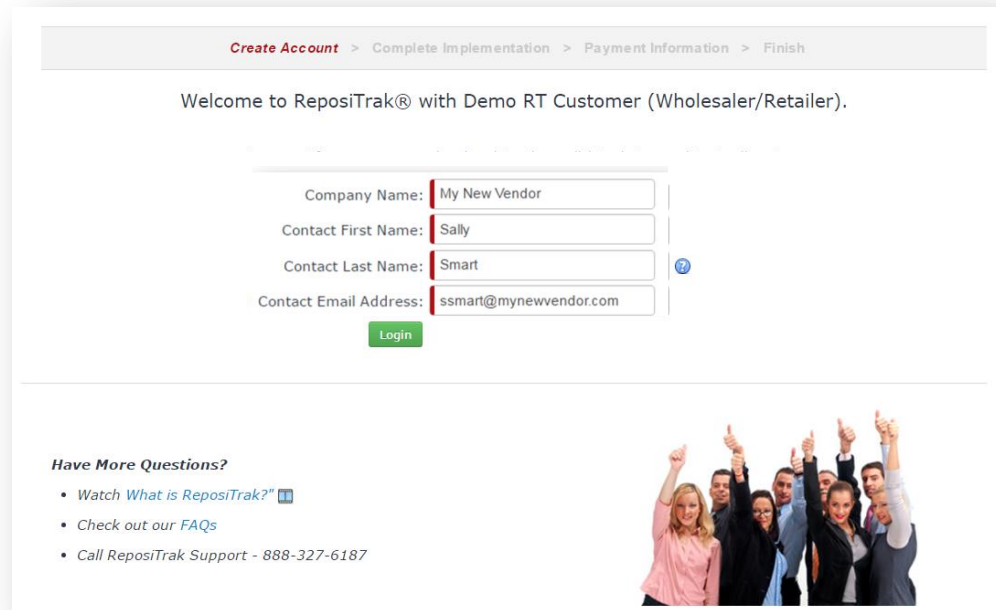
**Miscellaneous**

- Show Mailing Address



# The Invitation Packet Includes...

- A vendor letter, signed by you
- A link to a video webisode explaining:
  - Your initiative
  - FSMA requirements and tort risk
  - Why ReposiTrak?
- How to contact us
- A link to enroll online



Create Account > Complete Implementation > Payment Information > Finish

Welcome to ReposiTrak® with Demo RT Customer (Wholesaler/Retailer).

Company Name: My New Vendor

Contact First Name: Sally

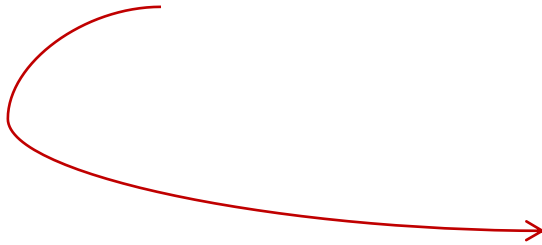
Contact Last Name: Smart

Contact Email Address: ssmart@mynewvendor.com

Login

Have More Questions?

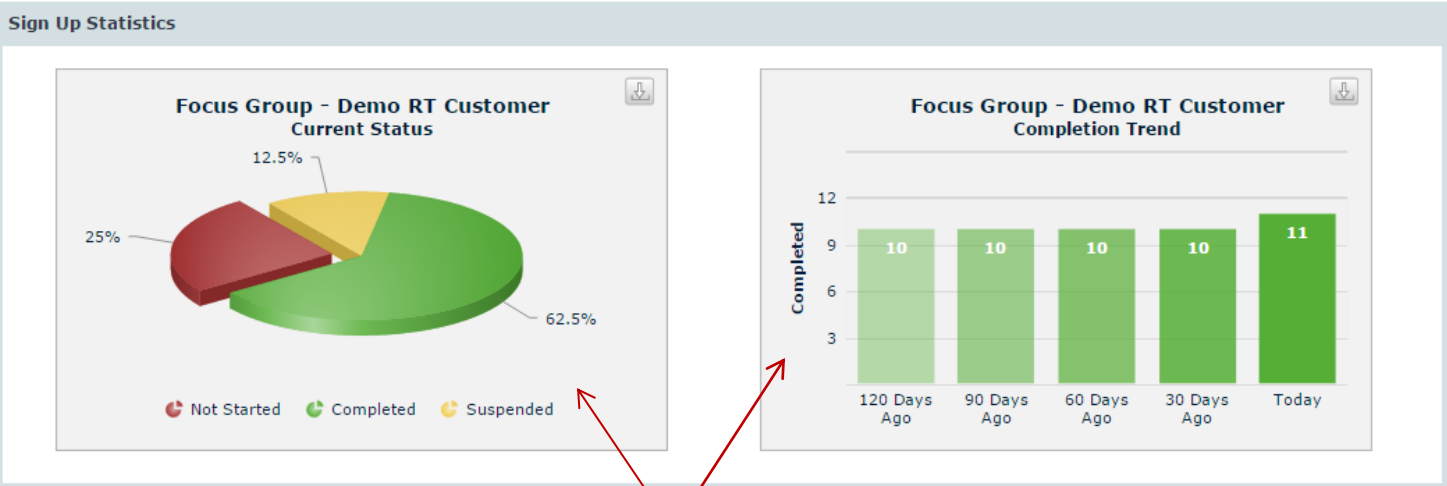
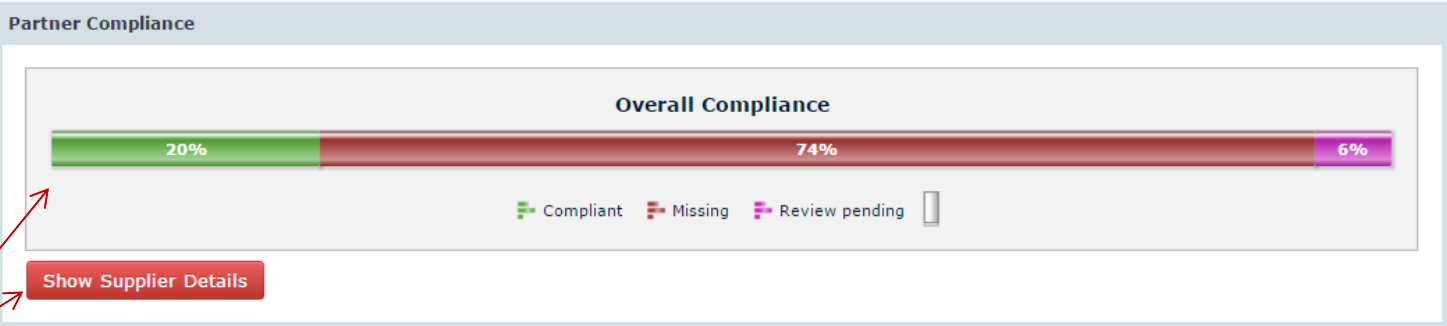
- Watch [What is ReposiTrak?](#)
- Check out our [FAQs](#)
- Call ReposiTrak Support - 888-327-6187



# Customer View

## Check on the Status of your Suppliers

**Compliance Center dashboard shows the compliance status for your overall program and by supplier**



**Tracks the progress of your supplier enrollment**



# Customer View

# We're Not Just an Electronic Storage Box

1. View by Supplier

or

2. View by Document

**Partner Selection**

Supplier: Demo RT Vendor 1 (18105) ▼  
Document: Please select Document ... ▼  
Document Category: All ▼  
Status: All ▼  
 Required Documents Only

**Documents**

Document	Partner	Status	Effective Period	Action
Certificate of Liability Insurance	Demo RT Vendor 1 (18105)	Pending Review Specs not met	02/01/2016 01/31/2017	Action ▼
Hold Harmless	Demo RT Vendor 1 (18105)	Missing	N/A	Action ▼
Letter of Continuing Guarantee	Demo RT Vendor 1 (18105)	Missing	N/A	Action ▼

**Documents**

Document	Partner	Status	Effective Period	Action
Certificate of Liability Insurance	Browns Bee Farm (18121)	Pending Review Specs not met	12/02/2015 12/01/2016	Action ▼
Certificate of Liability Insurance	Demo RT Vendor 1 (18105)	Pending Review Specs not met	02/01/2016 01/31/2017	Action ▼
Certificate of Liability Insurance	Laila's Treats (118404)	Missing	N/A	Action ▼
Certificate of Liability Insurance	Lexi's Treats (118496)	Missing	N/A	Action ▼
Certificate of Liability Insurance	Mimi's Treats (118509)	Missing	N/A	Action ▼
Certificate of Liability Insurance	Okie Oatmeal Cookies (18138)	Missing	N/A	Action ▼
Certificate of Liability Insurance	Park City Canning (18114)	Missing	N/A	Action ▼
Certificate of Liability Insurance	Park City Canning (18114)	Missing	N/A	Action ▼

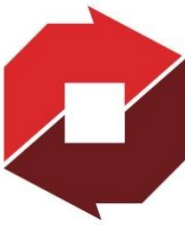
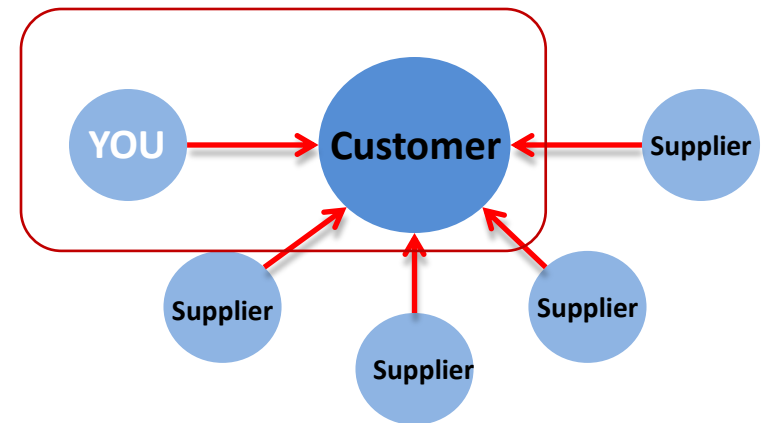
ReposiTrak reads inside the documents to flag exceptions:

- Missing
- Expired
- Specs Not Met
- All Exceptions



**As a supplier, here's how you will support a customer using ReposiTrak**

- 1) Enroll servicing facilities**
- 2) Upload required documents**
- 3) Address non-compliance issues & monitor overall status**



# Maintain Updated Facility Information

Company Name:

Contact First Name:

Contact Last Name:

Contact Email Address:

Contact Phone Number:

Partner ID:

**Mailing Address**

Address:

City:

State: Not Selected

Country: Not Selected

Zip Code:

**Partner-Specific Profiles**

Check at least one from each section and check all that apply.

	Profile Criteria	
<b>Billing Type</b>	Central Billing	<input type="checkbox"/>
	Warehouse Billing	<input type="checkbox"/>
<b>Category Manager #</b>	7 - TJG	<input type="checkbox"/>
	11 - JMA	<input type="checkbox"/>
	16 - NGH	<input type="checkbox"/>
	18 - JDP	<input type="checkbox"/>
	29 - MLK	<input type="checkbox"/>
	60 - DSS	<input type="checkbox"/>
	61 - CXB	<input type="checkbox"/>
	62 - PRS	<input type="checkbox"/>

Save

- Enter your company and contact information

- Configurable, partner-specific profile selections drive future activities and requirements

- Billing type, e.g. warehouse billing or central (DSD) billing



# Supplier View

## Upload Any Required Documents

Filter By

Partner: Demo RT Customer (Wholesaler/Ret... ▼

Document: All with Exceptions ▼

Document Category: All with Exceptions ▼

Status: All with Exceptions ▼

Required Documents Only

Documents

Document	Status	Effective Period	Partner	Action
Certificate of Liability Insurance	Specs not met	02/01/2016 01/31/2017	Demo RT Customer (Wholesaler/Retailer) (18096)	Action▼
Hold Harmless	Missing	N/A	Demo RT Customer (Wholesaler/Retailer) (18096)	Action▼
Letter of Continuing Guarantee	Missing	N/A		

**Become Compliant**

Add Document For Demo RT Customer (Wholesaler/Retailer) Document

Revoke Access From Demo RT Customer (Wholesaler/Retailer)

Add Note For Demo RT Customer

Help

Why Is It Listed For Demo RT Customer

Partner Contact Info

- If the Status is **Missing**, add it.
- If it's **Expired** or if the **Specs not met**, update it...

- Add or Update the specified document To *Become Compliant*.





# Supplier View Check on Your Compliance

**ReposiTrak**  
Track & Trace Brand Protection

Compliance Center | My Company | My Partners | Manage Documents | Track & Trace

Select Track & Trace Business Unit Compliance Center

Back

**Add Document**  
Not Selected [Go] [Show All]

**Overall Compliance Rating**  
**68.50%**  
View Scorecard

**Compliance Task List**

**All City Foods**  
0% 20% 40% 60% 80% 100% [Become Compliant]

**Centrally Located Grocers**  
0% 20% 40% 60% 80% 100% [Become Compliant]

**Message Center**

From	Subject	Action
ReposiTrak	Sign Up requested from Eastern Fine Wholesalers	[Sign Up]

**Latest Recalls**  
Miravalle Foods, Inc. Recalls Ground Annatto Because of Possible Health Risk

**Food Drug and Safety**  
Healthy People Targets: More need to be done  
Shopper Cards: The Pros Outweigh

- Quick view to your overall compliance rating

- Selecting “Become Compliant” kicks off a workflow process

- Message Center provides area for updated requests



# Questions? Our ReposiTrak Team is Here to Help



**Randy Fields**  
Chairman & CEO  
randy@parkcitygroup.com



**Christina Romas**  
Sr. Vice President  
cromas@parkcitygroup.com



**Leigh Feitelson**  
Bus. Development  
lfeitelson@parkcitygroup.com



**Joe Meherg**  
Vice President  
jmeherg@parkcitygroup.com

***Our contact us at [www.repositrak.com](http://www.repositrak.com) or 888-327-6187***

***Trusted Brand Protection***

