



# Welcome

OnTrak with FSMA: A Webinar Series

Hosted by: ReposiTrak<sup>®</sup>

# FSMA Finalizes Sanitary Transportation: Impact of Key Changes



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# 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 Now 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 17, 2016
2. Preventive Controls – Animal food	September 17, 2015	September 17, 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 31, 2016	May 31, 2017 ?

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

# FSMA Compliance at a Glance

	Produce Grower/ Farm	Manufacturing or Processing	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

# SANITARY TRANSPORTATION

# Who has to comply?

- Shippers
- Loaders
- Receivers
- Carriers



Engaged in transportation operations of food  
Applies to intrastate and interstate  
transportation

# Details on the Final Rule

## *Sanitary Transportation of Human and Animal Food; Final Rule*

Published in the *Federal Register* on April 6, 2016, Vol. 81, No 66, pages 20092-20170

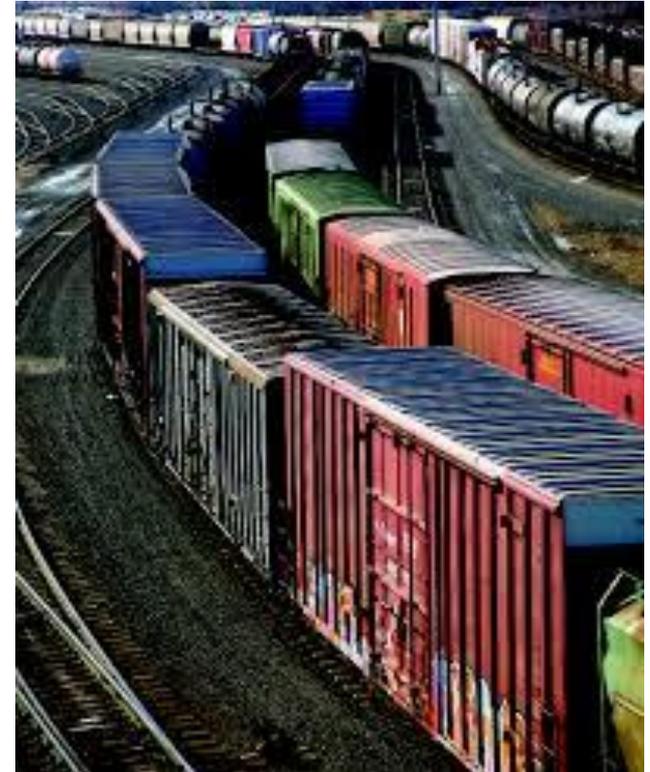


**FEDERAL REGISTER**

The Daily Journal of the United States Government

# Types of Transportation

- Motor and Rail



# Scope

## Applies to:

- Temperature controlled for safety (TCS) Foods
- Food not completely enclosed by a container
- Animal food (includes pet, animal feed, raw materials and ingredients)



## Exempt:

- Foods regulated exclusively by USDA
- Food that is completely enclosed by a container that is not TCS
- Compressed food gases
- Food contact substances as defined in section 409(h)(6) of the FDCA
- Human food byproducts for use as animal food w/o further processing
- Live food animals except molluscan shellfish

# Definitions



- **Shipper** – a person (manufacturer or freight broker) who arranges for the transportation of food in the US by a carrier or multiple carriers sequentially



- **Carrier** – person who physically moves food by rail or motor vehicle in commerce within the US. Does not include any person who transports food while operating as a parcel delivery service.

# Definitions



- **Loader** – person that loads food onto a motor or rail vehicle during transportation operations
- **Receiver** – any person who receives food at a point in the US after transportation, whether or not that person represents the final point of receipt for the food



# Intent of Rule



- FDA was required to issue regulations for shippers and carriers by motor and rail to use sanitary transportation processes to avoid creating food safety risks
- History of the regulation goes back to 2005 with the FDA and 1990 with Sanitary Transportation of Food Act (1990) assigned to DOT



# What is required?

- Vehicles and equipment must be cleanable and suitable to prevent food from becoming unsafe during transportation ops
  - Maintained in sanitary condition
  - Designed, maintained and equipped to provide adequate temperature control
  - Store in a manner to prevent pests



# Vehicle Operations

- Rules apply to all parties and roles might be combined
- Responsibilities may be reassigned through written agreements and contracts
  - Subject to records requirements



# Vehicle Operations (continued)

- Goal is to prevent food from becoming unsafe during transportation (examples)
  - Prevent cross contamination of raw foods and non-foods by segregation, isolation, and packaging
  - Handwashing to protect food in bulk vehicles or open containers
  - Temperature control of TCS products
  - Conditions depend on type of food – animal feed, pet food, human food and product stage

# Intra-Company Shipments

- “Common integrated written procedures” may be used for shippers, receivers, loaders and carriers under the ownership or operational control of a single legal entity.
  - This applies to the sections on the requirements for shippers, receivers and carriers.
  - Written procedures are subject to the records requirements



# Additional Provision

- Requirement to stop sale or distribution of food if shipper, loader, receiver or carrier becomes aware of “of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation”
  - Take appropriate action
  - Communicate with other parties
  - Determination by a qualified individual





# Shippers

- Specify in writing to the carrier and if appropriate the loader, the conditions for the sanitary specifications of the vehicle and equipment.
  - This includes design specs, cleaning procedures, sanitary conditions, temperature requirements including pre-cooling
  - Can be a one time written notification if the information does not change
  - Subject to records requirements

# Loaders

- Determine specific requirements for containers not completely enclosed to avoid contamination and evaluate condition (pests)
- Verify temperature requirements and condition of refrigerated storage



# Receivers



- Upon receiving TCS food, the receiver must *“take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food’s temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.”*



# Carriers

- Depending on the written agreement\*, the carrier is responsible for:
  - Equipment meets specs to prevent the food from becoming unsafe during transportation
  - If requested provide operating temperature and demonstrate temperature conditions were maintained (by agreed upon means)
  - Identify previous cargo for bulk containers, and information on most recent cleaning
  - Written procedures on sanitary condition of vehicles and equipment, transportation control, and bulk vehicle requirements

\*only applies when a written agreement is in place between shipper and carrier identifying the carrier as responsible for these activities

# Training

- Carrier must provide “adequate” training to personnel engaged in transportation operations
  - Potential food safety problems that can occur
  - Basic sanitary transportation practices
  - Responsibilities of the carrier
- Training required upon hiring and as needed
- Training records – date, type of training, and name of person trained



# Records

- Shippers and Carriers
  - Specific records requirements
  - Written agreements
- Intra-Company (single legal entity)
  - written procedures
- All records must be **kept for 12 months beyond when the procedures are in use**
- All records are required to be available to an duly authorized individual promptly upon oral or written request
- Carrier's written procedures must be onsite but offsite storage is permitted for all other records if accessible in 24 hours.
- Electronic records are onsite if accessible onsite



# Waivers

- PMO
  - Transportation of Grade A milk and milk products
- Retail Stores
  - As receiver (facility is under jurisdiction of the Food Code)
  - Direct to consumer transportation



FDA is planning to issue a final rule on waivers

# Compliance Dates

- One year compliance date
  - April 6, 2017
- Small Businesses
  - April 6, 2018
    - Non-motor carriers <500 FTE
    - Motor carriers <\$27.5 million in annual receipts



# Help from FDA?

- FDA Technical Assistance Network (TAN)
  - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- Stated an online training course is in development
- Stated a guidance document is in development





# SUMMARY

# Key Considerations for Sanitary Transportation

- Applies to shippers, carriers, loaders and receivers
- Covers food transported Interstate as well as Intrastate
- Valid for human or animal food shipped via rail or road
- Focuses on temperature control and avoiding contamination of products
- All records must be **kept for 12 months beyond when the procedures are in use**



# Impact: Sanitary Transportation

- Retailers/Wholesalers
  - Communication with carriers
  - Avoiding contaminating product
  - Increased procedures and records
- Manufacturers
  - Can perform any role in transportation
  - Avoiding contaminating product
  - Increased procedures and records



# Sanitary Transportation: Required Records

- Written agreements between parties
- Written standard operating procedures
- Key difference – Records must be kept **12 months beyond** when the procedures are in use



# Sanitary Transportation: Your To-do List

Task	Retail DC	Wholesaler	Manufacturer
Identify your role in transportation	✓	✓	✓
Put appropriate procedures in place	✓	✓	✓
Put appropriate training in place	✓	✓	✓
Put recordkeeping in place	✓	✓	

## Do these apply?

Yes, if you pack, ship, load, carry or receive food. See rule exemptions for details.

# Thank You!

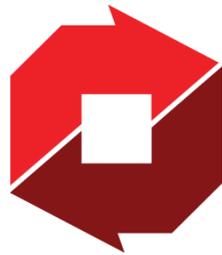
- **Interest in food safety**
  - Compliance with FSMA requirements
  - Preventive risk management
- **ReposiTrak supporting SQF user experience**
  - Easier registration
  - Faster audit results
- **Have asked ReposiTrak to go deeper into food safety**
  - Food Safety Plan management
  - Quality assurance



# For Help

- **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/>

# Industry Standard Food Safety Platform



ReposiTrak

*Trusted Brand Protection*

## Co-founders



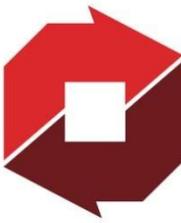
## Two Components



**Compliance  
Management**

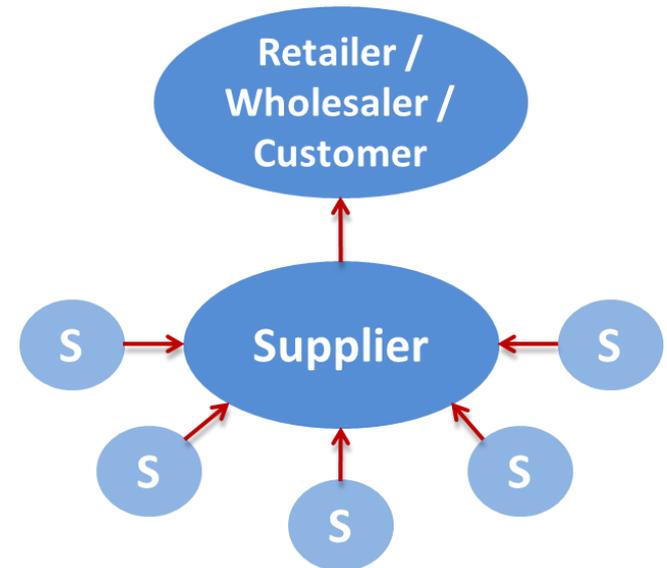


**Track & Trace**

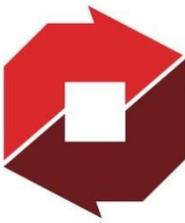


# 1-Stop System for All Compliance Records

- 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*



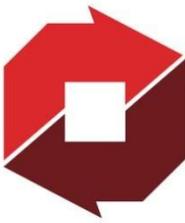
# Our Active Approach? A Dedicated Team



- We provide a dedicated staff
- We clean AND build your supplier contact list
- We reach out to every supplier and follow up until enrollment is complete
- We ACTIVELY follow up with suppliers to correct non-compliance

**70%**

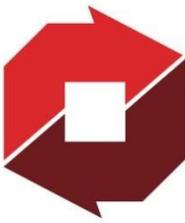
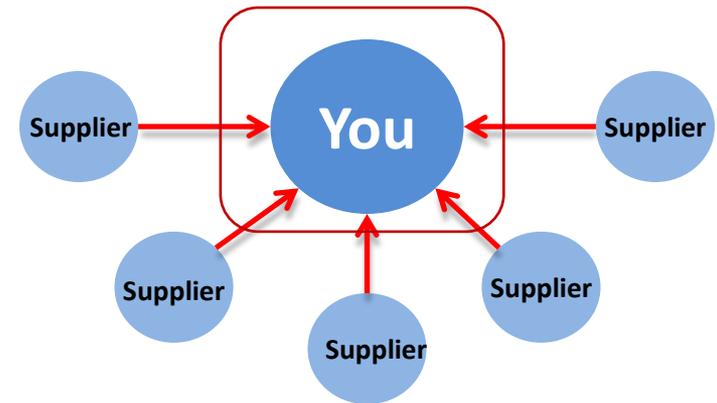
**Average decline in  
Non-Compliance  
among new users  
on ReposiTrak**



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

## Three main activities in ReposiTrak

- 1) Invite suppliers to enroll in ReposiTrak
- 2) Monitor overall compliance and enrollment stats
- 3) Manage non-compliance issues by supplier



# Invite New Vendors to Enroll in ReposiTrak

Enter **FOUR** pieces of information:

Company Name:	My New Vendor
Contact First Name:	Sally
Contact Last Name:	Smart
Contact Email Address:	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**

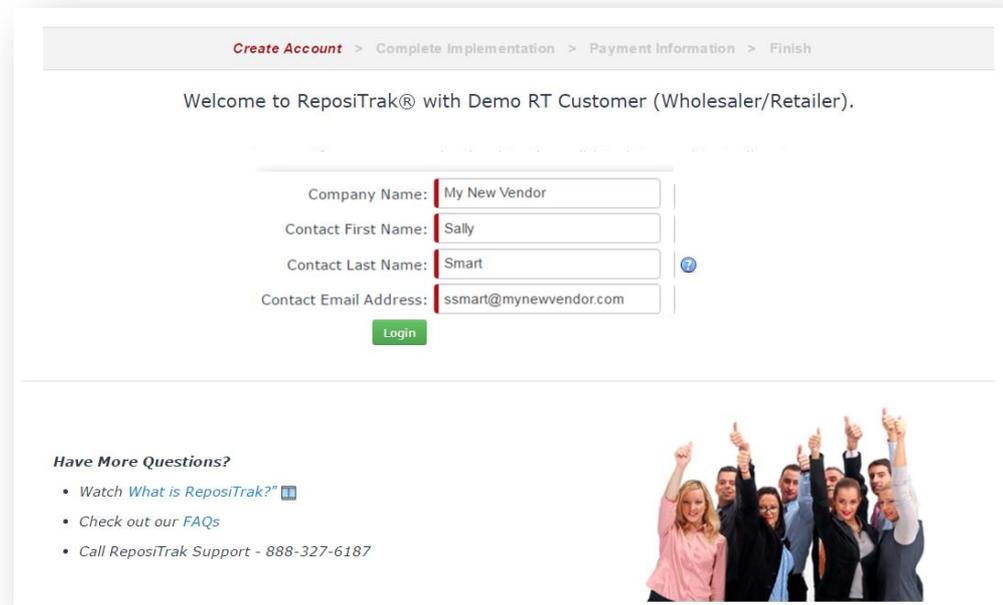
**Miscellaneous**

- 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

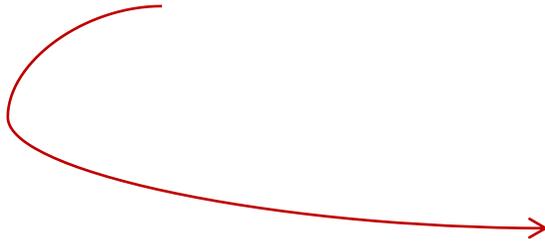
Contact Last Name: Smart

Contact Email Address: ssmart@mynewvendor.com

Login

**Have More Questions?**

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

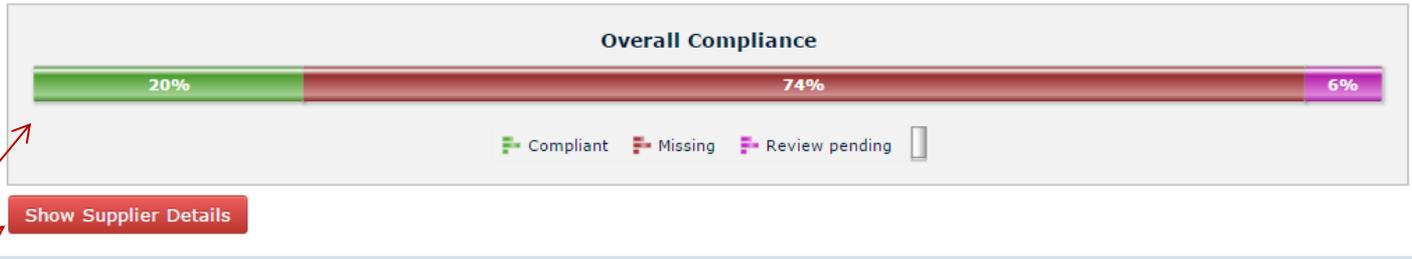


# Customer View

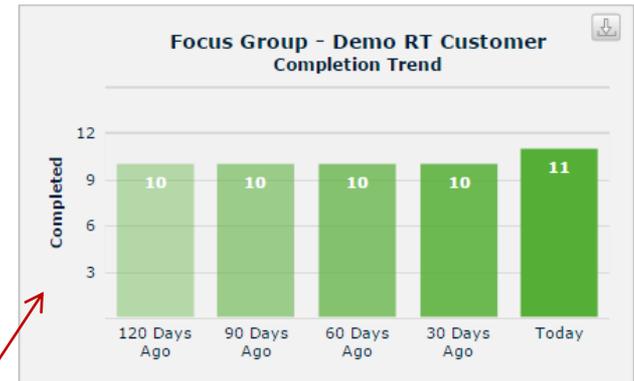
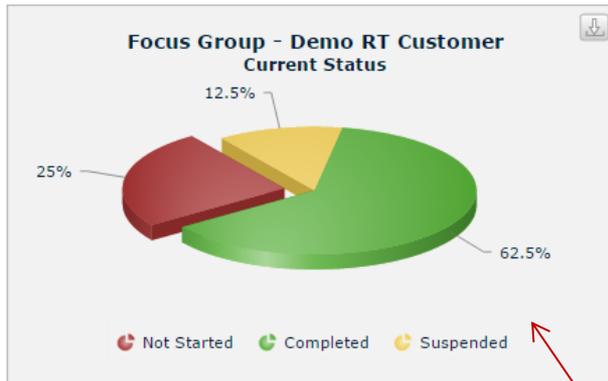
## Check on the Status of your Suppliers

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

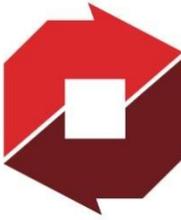
### Partner Compliance



### Sign Up Statistics



Tracks the progress of your supplier enrollment



## Two Ways to View Non-Compliance Issues

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**

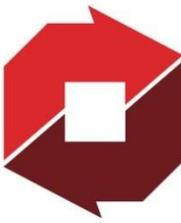
Document	Partner	Status	Effective Period	Action
Certificate of Liability Insurance	Demo RT Vendor 1 (18105)	Pending Review Specs not met	02/01/2016 01/31/2017	Action
Hold Harmless	Demo RT Vendor 1 (18105)	Missing	N/A	Action
Letter of Continuing Guarantee	Demo RT Vendor 1 (18105)	Missing	N/A	Action

**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

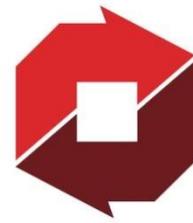
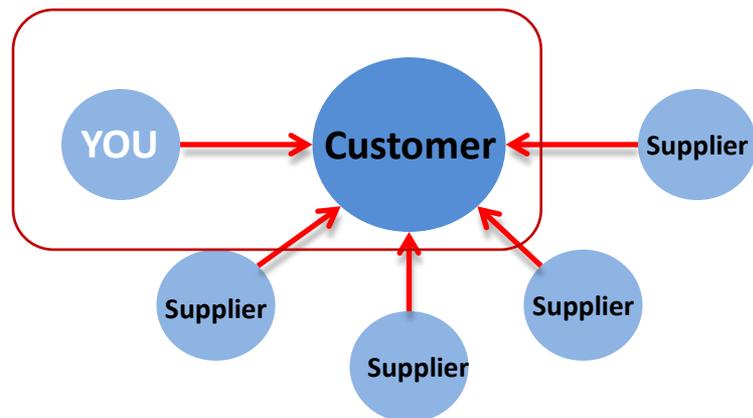
Just select the compliance status of interest:

- 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.

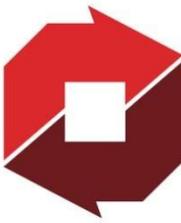
	Profile Criteria	
<b>Billing Type</b>	Central Billing	<input type="checkbox"/>
	Warehouse Billing	<input type="checkbox"/>
<b>Category Manager #</b>	7 - TJG	<input type="checkbox"/>
	11 - JMA	<input type="checkbox"/>
	16 - NGH	<input type="checkbox"/>
	18 - JDP	<input type="checkbox"/>
	29 - MLK	<input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

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

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)

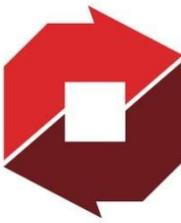
Add Note For Demo RT Customer (Wholesaler/Retailer)

### Help

Why Is It Listed For Demo RT Customer (Wholesaler/Retailer)?

Partner Contact Info

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



# Supplier View

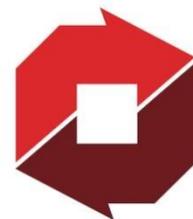
## Check on Your Compliance

The screenshot shows the ReposiTrak interface for a supplier's compliance center. At the top, there's a navigation bar with tabs for 'Compliance Center', 'My Company', 'My Partners', 'Manage Documents', and 'Track & Trace'. Below this, a breadcrumb trail reads 'Select Track & Trace Business Unit > Compliance Center'. A 'Back' button is visible. The main content area features an 'Add Document' section with a dropdown menu set to 'Not Selected' and a 'Go' button. To the right, the 'Overall Compliance Rating' is prominently displayed as 68.50% in green, with a 'View Scorecard' button below it. The 'Compliance Task List' section contains two progress bars: one for 'All City Foods' at approximately 85% and another for 'Centrally Located Grocers' at approximately 50%. Each progress bar has a 'Become Compliant' button to its right. Below this is a 'Message Center' table with one entry: 'Sign Up requested from Eastern Fine Wholesalers' from 'ReposiTrak', with a 'Sign Up' button. At the bottom, there are sections for 'Latest Recalls' and 'Food Drug and Safety'.

- 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



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