

**Leverage Your Supplier
Approval Program to
Proactively Reduce
Your Risk**



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Leverage Your Supplier Approval Program to Proactively Reduce Your Risk

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Today's Webinar

- FSMA...It's what's driving change
- The true cost of a recall
- "I'm not in charge of food safety"
- Finding and filling the gaps



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FSMA, IT'S WHAT'S DRIVING CHANGE



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FSMA's Magnificent Seven, Final Rules

- Preventive Controls for Human Food, **August 30, 2015**
- Preventive Controls for Animal Food, **August 30, 2015**
- Produce Safety, **November 13, 2015**
- **Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, November 13, 2015**
- Accredited Third-Party Certification, **November 13, 2015**
- **Sanitary Transportation, March 31, 2016**
- **Intentional Adulteration, May 27, 2016**



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FSMA, are you ready?

- A written food safety plan
- Hazard analysis
- Preventive controls
- Monitoring
- Corrective actions and corrections
- Verification
- Supply chain program
- Recall plan
- Associated records

“Preventive Controls Qualified Individual”



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FSMA Investigation Standard

- If the FDA believes that there is a **reasonable probability** that the use of or exposure to an article of food and, any other article of food that the FDA **reasonably believes** is affected in the same manner, will cause serious adverse health consequences or death to humans **or animals**.
- Each person (excluding farms and restaurants) who **manufactures, processes, packs, distributes, receives, holds, or imports** such food article shall, at the request of a FDA officer or employee and, upon receipt of written notice, **must provide access to and a copy of all records relating to such food articles**.



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FSMA Records

Record Keeping/Response to FDA Record Requests

- The Proposed Rule will require facilities to submit or produce documents “promptly.” As provided in the rule, **“promptly” means 24 hours.**
- Because facilities will be required to maintain and update the necessary documentation at all times and as a matter of routine practice, any response that will require more than 24 hours will be a red flag.



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Food Safety Enforcement Tools

- Warning letters
- Recall
- Restraining order or injunction
- Notice of suspension
- Seizure, Quarantine
- Administrative detention
- Suspension of registration
- Criminal Prosecution



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THE TRUE COST OF A RECALL



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2016 Recalls – Ingredients

1. **Nestlé:** glass in spinach - DiGiorno, Lean Cuisine, Stouffer's
2. **CRF Frozen Foods:** 350 food products - 42 brands - organic
3. **Grain Craft:** customers - Hostess, Kellogg, Mars, Frito-Lay
4. **SunOpta:** facility closed 4/21-6/1 (8-month recall period)
5. **General Mills:** 42 people in 21 states sickened by E. coli
6. **National Frozen Food:** 9-month production period
7. **Egyptian strawberries:** 9 states and 134 sickened – larger?



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Strawberries: Supply Chain Nightmare

International Company for Agriculture Production & Processing's (ICAPP) statement on **October 31, 2016**:

“We do not distribute them in the United States. And while we’re working closely with the FDA to ensure that the supply of frozen strawberries exported to the U.S. are safe and healthy, we do not yet have complete information about downstream distribution.”



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Strawberries: Supply Chain Nightmare

- **What's in your supply chain?**
- Initial investigation: **early August 2016**
- ICAPP's statement: **October 31, 2016**
- **November 2nd**: FDA – other foodservice operators
 - CDPH announces: **3,000** retailers, schools, restaurants and other entities received strawberries
- Time is of the essence – **two weeks** for customers exposed to Hepatitis A
- How would you explain to customers and consumers? – **We didn't know. . . .**



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Recall: Stakeholder Impact

- **24/7 Media:** How will you respond?
- **Customers** are calling, emailing . . .
- **Suppliers** have questions.
- **Investors** need answers.



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Recall: Financial Implications

What is the cost of **YOUR** recall?



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Average Cost of a Food Recall

\$30 million

Capturing Recall Costs, Oct. 2011

\$10 million

Recall Execution Effectiveness, June 2010



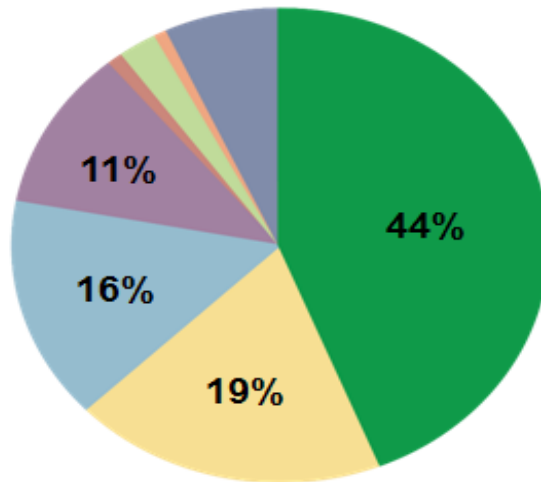
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Do Not Underestimate Your Exposure

RGL Forensics

Business Income Losses in Recall Events



All Losses

Less than 10% not indicated.

Key

- Business Income Loss
- Inventory Loss
- Cost of Refunds
- Recall Expenses
- Destruction Costs
- Other Costs / Clean Up
- Recall / Legal Consultant
- Third Party Claimed Expenses



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Lost Profits: Will Your Customers Stay?

Customer	2017 Projected Sales %
Walledmart	46%
CostingCo	21%
TradingJane	17%
Targeted	9%
GoingGoingGone	7%



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Recall: Legal Impact

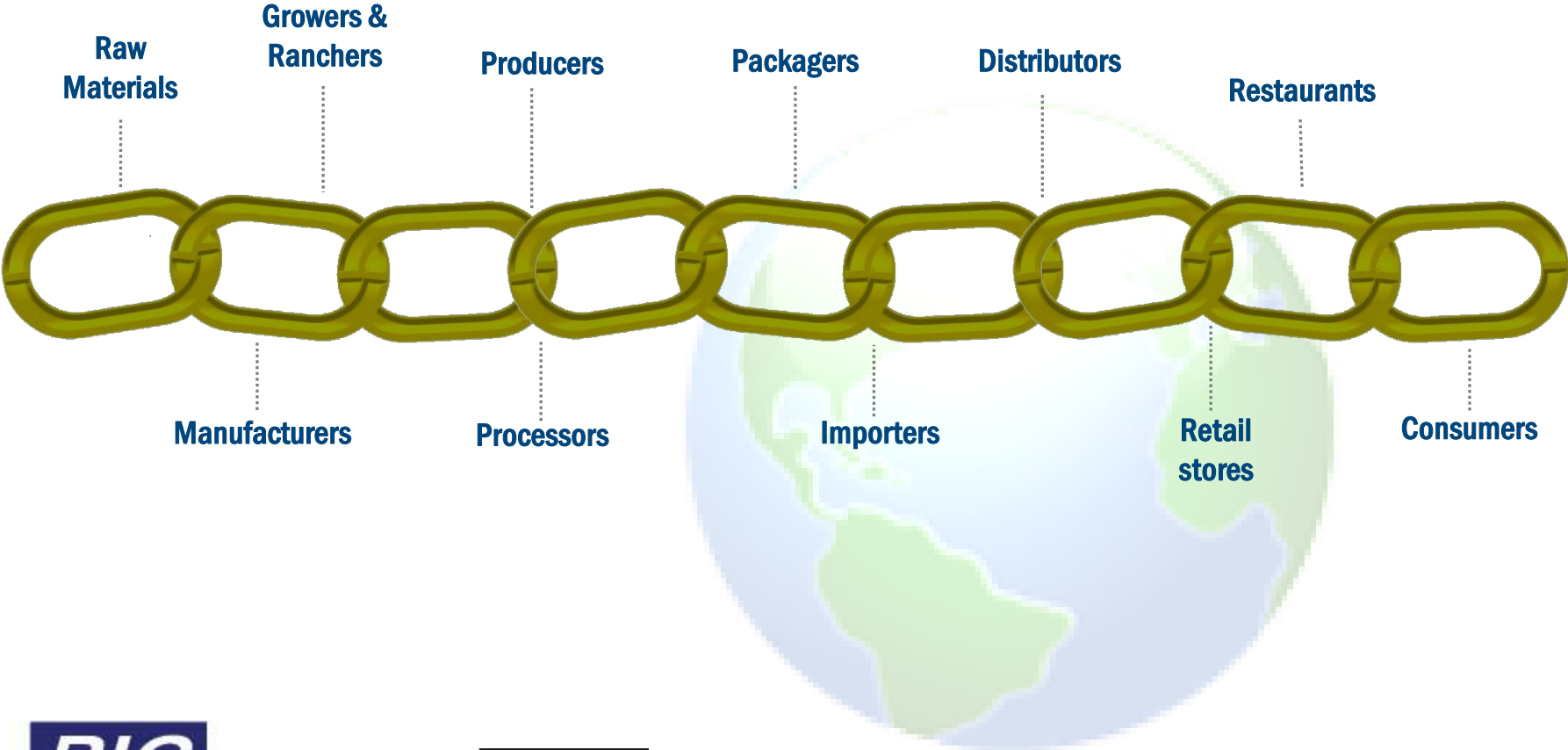
- Supply Chain “Strict” Liability
- Prosecution of Criminal “Strict” Liability



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Supply Chain Strict Liability



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Criminal Strict Liability

- Federal Food, Drug and Cosmetic Act (FDCA): allows for criminal prosecution.
- Prosecution basis (*United States v. Park*):
 - committed a prohibited act;
 - caused another to commit a prohibited act; or
 - had a **“responsible relation”** to the commission of such prohibited act.
- **Accountability:** person had position, responsibility or authority to prevent or promptly correct a violation and failed to do so.
- **Food + adulteration + introduction into interstate commerce = FDCA violation!**



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Fines, Jail, Lifetime Bans

- Michelle Myrter, **president**, Castle Cheese Co. (2016)
- William Aossey, Jr., **founder**, Midamar Corp. (2016)
- David Romero, **principal**, Global Nutrients, Stella Labs, Nutraceuticals (2016)
- Jesse “Babe” Amaral Jr. and Robert Singleton, **co-owners**; Felix Cabrera, **foreman**; Eugene Corda, **yardman**, Rancho Feed Corporation (2016)
- Soo C. Park, **owner** and **president**, Henry’s Farm, Inc. (2016)
- Austin “Jack” DeCoster and Peter DeCoster, **owners**, Quality Egg, LLC (2015)
- Stewart Parnell, **owner** and **president**; Michael Parnell, **broker**; Daniel Kilgore and Samuel Lightsey, **plant managers**; Mary Wilkerson, **QA manager**, PCA (2015)
- Eric Jensen and Ryan Jensen, **principals**, Jensen Farms (2013)
- Are Blue Bell, Chipotle, Dole, CRF or General Mills executives next?



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“I’M NOT IN CHARGE”



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Food Safety is Everyone's Problem

- Recent statistics from a group of audited manufacturers indicate 31% of recalls were caused by their ingredient suppliers.



- How did the supplier get approved?



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A Typical New Vendor Process ...

- New vendor meets with buyer
- Buyer evaluates product
- Credit application requested/processed
- Vendor number assigned
- Purchase order placed
- Was the vendor approved?
 - What does 'approval' mean to your company?



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Use the Supplier Approval Program to Reduce Risk: Close the Gaps

- **Vendor Agreements**
- **Environmental testing, where applicable**
- **Traceability (one forward/one back)**
- **Testing batch & lot**
- **Hazard analysis & preventive controls in place**
- **Liability Acknowledgements from the vendor**
 - **Certifications specific to meat suppliers**
 - **Certifications that vendor is FSMA compliant**
 - **General liability**
 - **Damages resulting from recall**



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FINDING & FILLING THE GAPS



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Will Your Insurance Cover a Recall?



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Recalls are NOT Covered

Property Policy

- No direct physical loss
- Exclusions

General Liability Policy

- No bodily injury / property damage
- No personal injury
- Economic costs not covered
- Exclusions

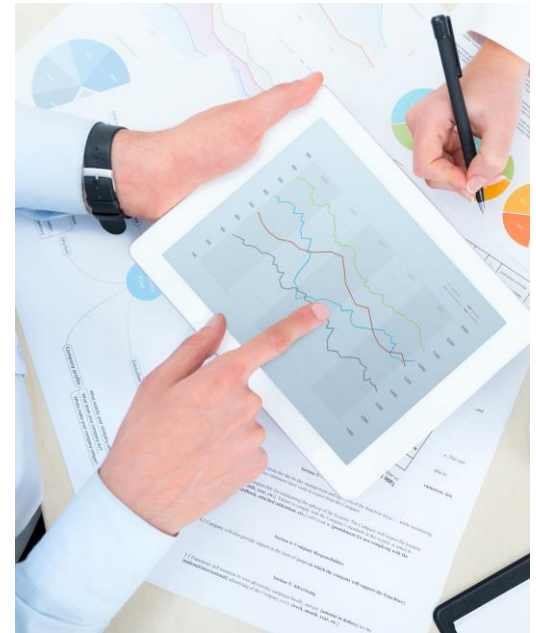


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Claims Mitigation and Enterprise



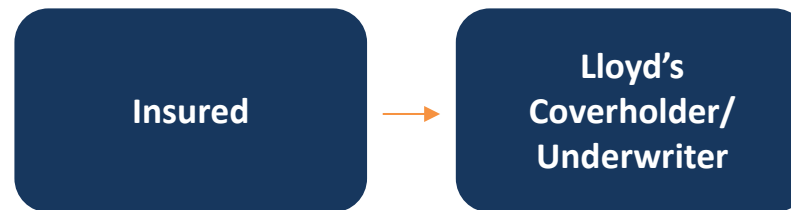
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Traditional Structure to get Insurance



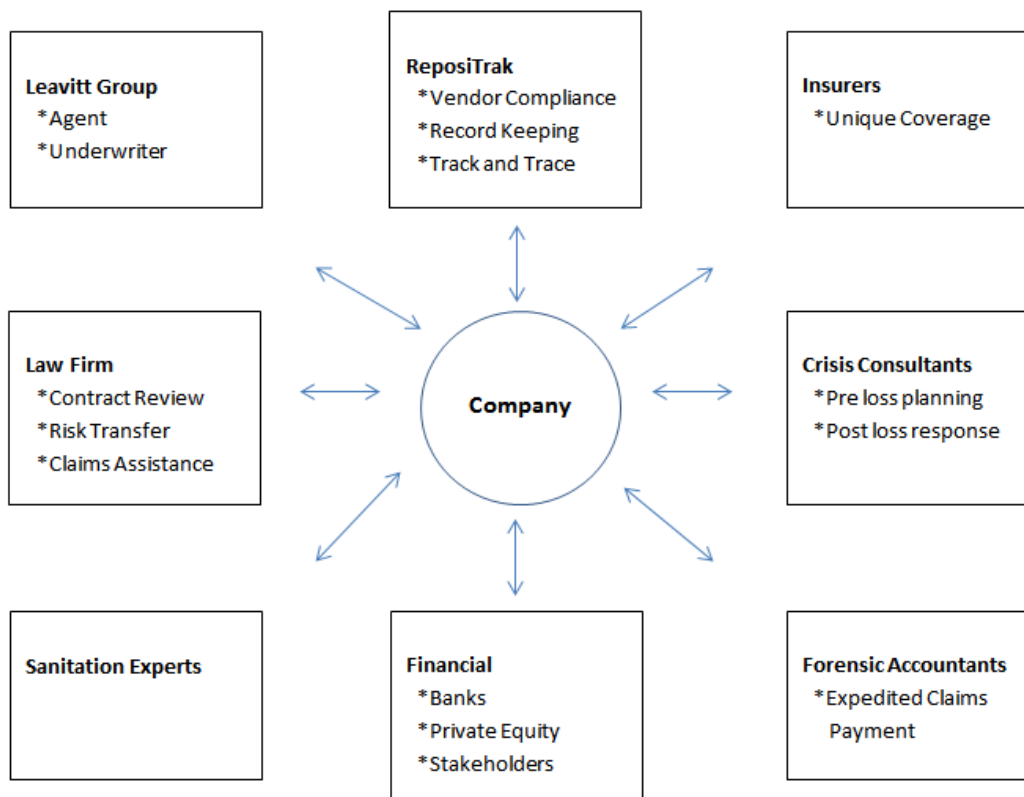
Leavitt Group Model



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Leavitt's Strategic Partner Network



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Valued-added Services

- Risk profiling / hazard analysis
- Supply chain risk analysis
- Insurance gap analysis
- Business resilience after a loss



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Starting Point: Perform Risk Analysis

- Understand exposures to loss
- Review your customer vendor supply agreements
- Review your suppliers and the supply contracts
- Review private label agreements
- Quantify probable loss & understand your objectives
- Review current insurance structure
- Offer recommendations with associated cost/benefit



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Product Contamination Insurance

- Includes pre- and post-crisis consultants' costs
- Insured Event:
 - Accidental contamination
 - Malicious tampering
 - Product extortion
 - Governmental recall
 - Adverse publicity



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Product Contamination Insurance

Loss includes the reasonable and necessary expenses or costs listed and incurred by the Insured directly or solely in connection with a covered Insured Event:

- Pre-recall expenses
- Recall costs (including redistribution costs, replacement costs, third party recall)
- Business interruption (loss of gross revenue and extra expense)
- Rehabilitation expense
- Extortion costs
- Consultants' costs
- Third party loss (including customer business interruption)



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Innovating Coverages for YOUR Unique Exposures

- Recall exposure is specific to each company
- We have created **new policies**
 - Meeting industry needs
- We have designed new endorsements:
 - **Criminal Strict Liability**
 - **Third Party Crisis Consultant Costs**
 - **Expedited Claim Preparation**



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Other Business Risks to Consider

- Stability of lender's credit lines
- Vendor solvency (multiple customer exposure)
- Foreign supplier verification – new rules
- Sanitary transportation – new rules
- Inventory delay, detention, refusal
- Trade credit
- Management liability, employment practices & cyber



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Questions?



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