

# USING PREDICTIVE ANALYSIS FOR CONTINUOUS IMPROVEMENT AND MONITORING



MESH INTELLIGENCE

**fdaimports.com**

# PRESENTED BY

---



**Shub Debugupta, PhD**

Founder/CEO of Mesh Intelligence

[shub@meshintel.com](mailto:shub@meshintel.com)

1.202.674.6870



**Benjamin England, Esq.**

Founder/CEO of FDAImports.com  
& Benjamin L. England & Assoc.

[blengland@fdaimports.com](mailto:blengland@fdaimports.com)

1.410.220.2800



# AGENDA

---

- I. Food Safety and Risk
- II. Risk Prediction
- III. Real World Uses of the Data
- IV. Conclusions and Q&A

# FOOD SAFETY AND RISK

---

## FSMA is about Risk Mitigation

### From reaction to prevention

- More foreign facility FDA inspections
- Import Certifications (VQIP)
- Foreign Supplier Verification Program
  - Importers are legally responsible to *verify* supplier compliance
  - Importers must import from “approved” suppliers

### Food Safety Plans

- How do you continuously monitor a foreign supplier?
- How do you ensure continuous improvement of your FSP/FSVP?

# FSMA AND FSVP, generally

## Most Activities are still SNAPSHOTS or OLD NEWS

- Hazard Analyses (Biological, chemical, physical, unapproved additives, etc.); Inherent Risks
- Compliance history of each supplier (IA's, WL's, 483s)
- Verification Activity (Annual on-site audits, Sampling and testing, Review food safety records)
- Corrective Actions

## FDA does not use this model to target for a reason

- Too myopic
- Backwards looking
- Narrow field of vision; tunnel vision



# REGULATORY DATA

## What is it?

- May Proceeds
- Releases
- Documentation reviews
- Examinations
- Samples
- Detentions
- Refusals
- Import Alerts

## What does it reveal?

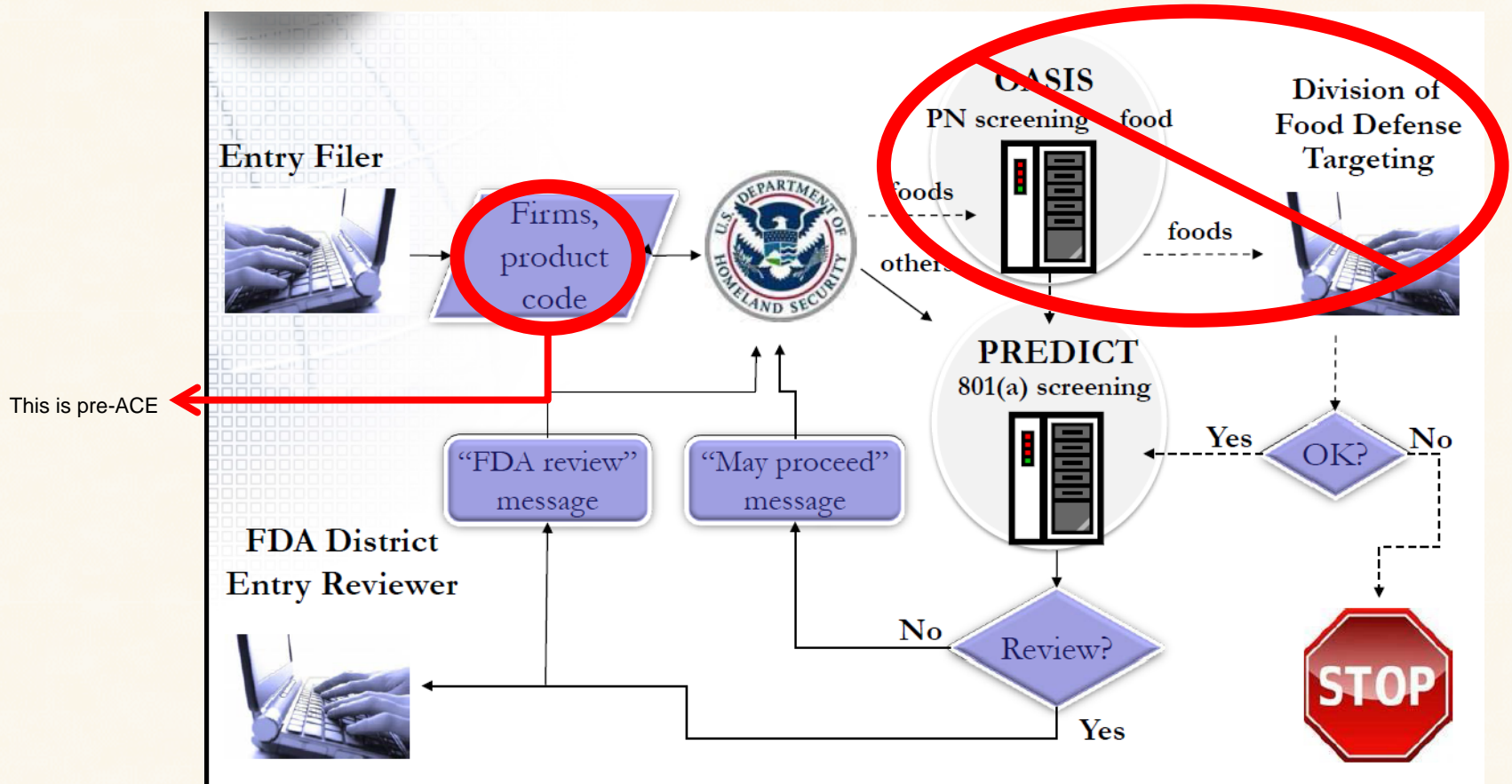
- Current status
- Historical compliance
- Negative and Positive
- Repeat problems
- Regional problems

# FDA'S PREDICT

- Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (cir. 2002)
- Improved FDA import targeting on a line-by-line basis based upon RISK factors
- Ensures visibility and accountability in risk-based decision making
- Significantly increased the Source and Variety of risk assessment data
- FDA reports venture into AI Pilot



# FDA REVIEW, PART 1

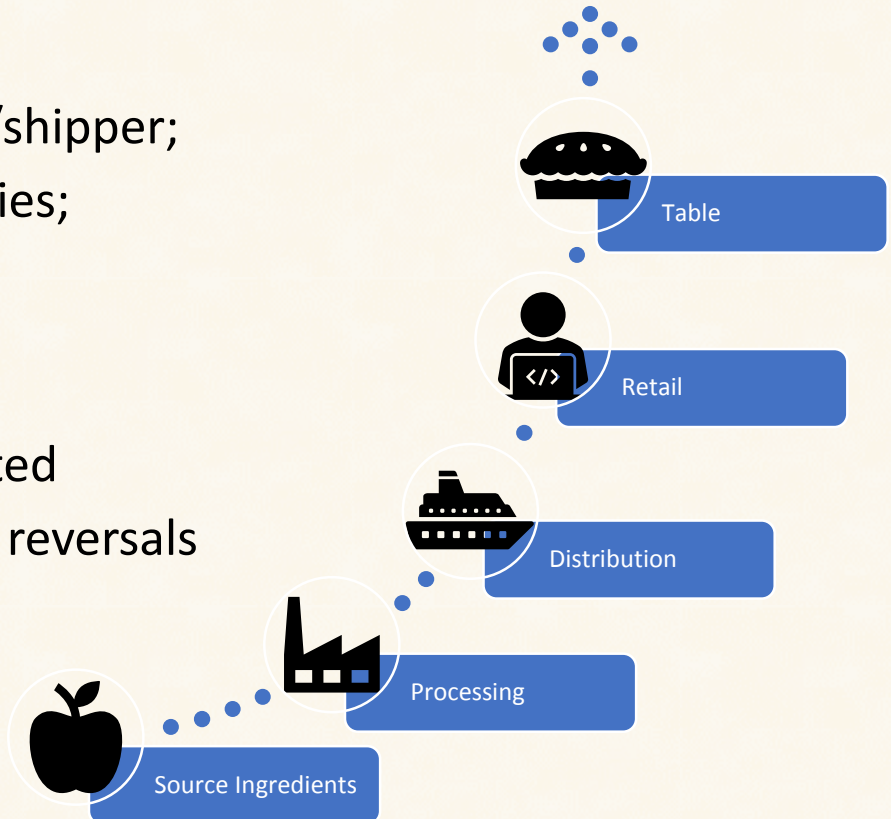


Taken from FDA, Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)



# SUPPLY CHAIN DATA

- What is it?
  - Shipping Data; Manufacturer/shipper;  
Shipping trends and frequencies;  
Relationships among parties;
- What does it reveal?
  - Shipping anomalies; unexpected  
Changes infrequencies; Trend reversals  
Business Behavioral Shifts
- How is it being used now?



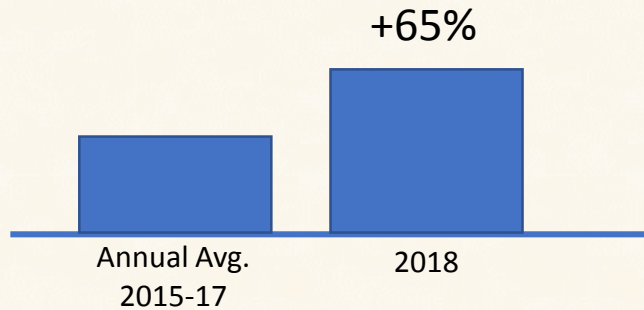
# AGENDA

---

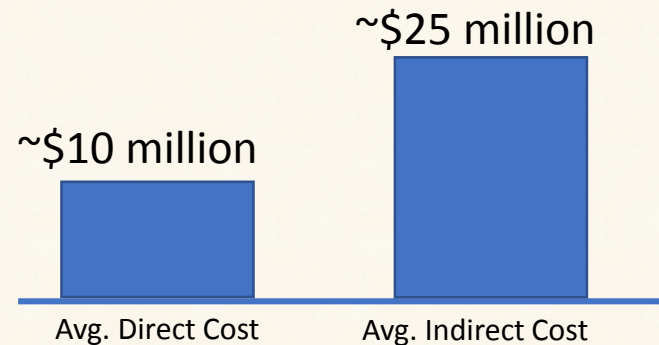
- I. Food Safety and Risk
- II. Risk Prediction
- III. Real World Uses of the Data
- IV. Conclusions and Q&A

# Risk is rising and the cost of errors are rising even faster

Food safety violations are increasing  
(Infections diagnosed by CIDT)



Recalls have high direct costs;  
indirect costs even higher



Almost every organization in the food industry faces **growing food safety and reputation risk** because of irreversible factors:

This is being driven by:

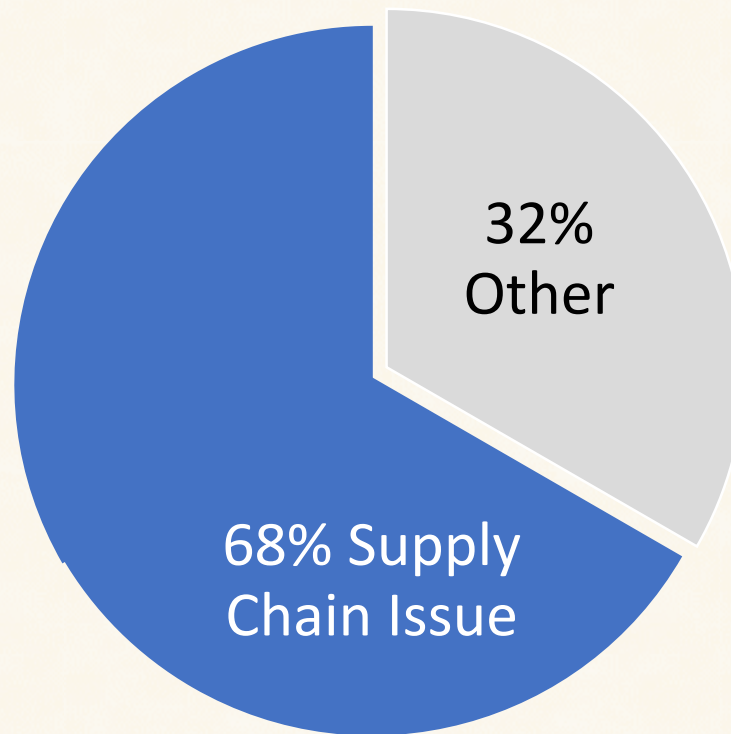
- Growing **supply chain complexity**;
- Changing global supply chains driving **velocity, volume** and **tariffs**; and
- Heightening and new **regulatory** and **traceability** requirements (e.g. US FSVP)



# Risk can be in your control

---

Survey of 120 Food Recall Post-Mortems  
2017



# Knowing where to look

---

Only a small portion of supplier and supply chain data is currently being used for food safety and food security risk management

## Internal Data

Food inspection and testing data and contractually available information

## Challenges

- Tends to be backward looking
- “Best foot forward”
- Single company specific (not network)



## External Data

The digital stream of supplier and supply chain data, their partners and regulatory outcomes

## Challenges

- Volume
- Siloed and non-standardized
- Signal-to-noise

# Powerful assets underlying risk prediction

---

Using **Supply Chain** and **Regulatory Activity** and **Regulatory Outcome** data for **Continuous Monitoring** and **Continuous Improvement** of the firm's Food Safety and Security Program

## **What Regulators Do** **“Regulator View”**

A unique view into FDA's historical actions, trends and behaviors and their likely actions. Key regulatory actions and filings are tracked and predicted

## **How Products Flow** **“Industry View”**

An industry-, competitor- and peer-view of related food products and ingredients flowing through global supply chains

## **What the Organization is Doing** **“Internal View”**

An analysis of food safety data including vendor audits, reports and reviews internal to the Organization and their vendors/suppliers



# New data and analytical tools allow you to move towards a forward-looking view on risk

---

## *Traditional View*

Going from asking “What happened?” ...

- Incident reports
- Audit and inspection reports
- Violation information
- Regulatory filings
- Internal or partner audit reports



## *Expanded View*

...to understanding “How are they behaving?” ...

- Environmental context determinants – economics, industry, mobility, connectedness
- Behavioral data – actions taken before and after; actions taken by related partners/parties
- Internal data – personnel turnover

...and then using powerful tools to recognize patterns and predict what will likely happen and to manage risk

# AGENDA

---

- I. Food Safety and Risk
- II. Risk Prediction
- III. Real World Uses of the Data
- IV. Conclusions and Q&A

# REAL WORLD USES OF THE DATA

---

- **Ex #1: Food Ingredients** - Detection of competitor's false declaration of foreign manufacturer (on FDA Import Alert for illegal or above tolerance pesticide chemical residues) resulting in importation of adulterated food ingredients
  - **Outcomes:** FDA enforcement against importer; considering Lanham Act case initiation
- **Ex #2: “Organic” Foods** - Detection of foods declared as “organic” processed in facility lacking organic certification (shipment patterns masked in manifest data, detected in manufacturer source data)
  - **Outcomes:** FDA and USDA investigations (administrative, potential criminal)



# Lactalis 2017/2018 salmonella case: Could a new approach have helped buyers reduce their risk?

---

## Demonstration Description

To use our unique data and our data science capabilities to evaluate a specific incident – the salmonella outbreak at Groupe Lactalis S.A., France in 2017 – and assess whether our data would have predicted the incident.

### About Groupe Lactalis S.A.

- Privately held
- Founded 1933 in Laval (France)
- Revenue: \$20+ Billion (est. 2017)
- Sites: 220 sites globally
- Employees: 75,000+ in 85 countries
- Ships 5,000+ containers of product across international borders annually
- Limited reporting – Company does not publish list of owned brands; clients/accounts

### Incident: Salmonella triggered recall of baby food products, Dec 2017

- One of the largest European food recalls
- Bacteria traces at Craon factory suspected as early as 8/2017 (NYTimes)
- Official French Govt announcement 12/2017; recall announced 12/2017
- 7,000+ tons of baby milk powder (12MM boxes) recalled across Asia and Europe; USA not directly part of recall

# Indication of a significant unexplained operational issue at Lactalis beginning July 2017 (4 months early)

## Legacy Approach “Analyze what is said”

- Reviewed Lactalis corporate information, filings, reviews and food safety inspections between 6/17 to 12/17
- Veterinary inspection at Lactalis’s Craon location in 9/17 by French Ministry of Agriculture “did not see anything”

### Results

A conventional risk detection approach would have been unable to identify an issue or risk



## Augmented Approach “Analyze what is done”

- A review of Lactalis business behavior in context identified FOUR risk flags
- Our analysis would have predicted upcoming risk due to unexplained activity
- We would have recommended further review

### Results

An augmented risk detection approach identified risk flags beginning July 2017 and would have recommended additional steps

# Unique and powerful growing data assets



## Unique regulatory and compliance intelligence

Database of FDA's historical regulatory actions and risk indicators.

### FDA import review and action data

- May Proceeds
- Releases
- Documentation reviews,
- Examinations
- Samples
- Detentions
- Refusals
- Import Alerts (daily over time)

## Supply chain and ingredient flow intelligence

Database of supply chain transaction data and product detail.

### Millions of food shipments tracked globally

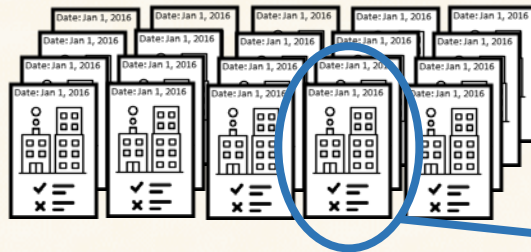
Supply chain data at the buyer-, seller-, shipper-level and product-level

- Product, size, weight and volume information
- Route, shipper and port information
- Some pricing information
- Company financial, personnel and legal information

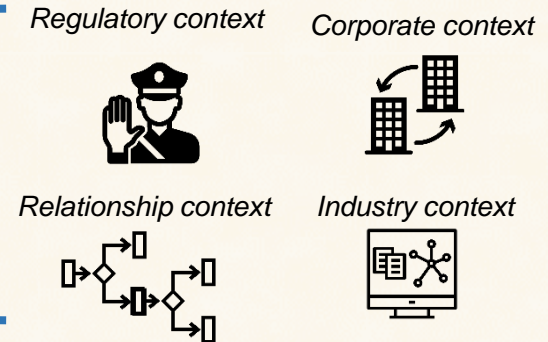


# Our incident risk prediction engine aims to recognize patterns in known incidents to trigger early action

1. Information on every (past and current) publicly-available incident and violation is collected

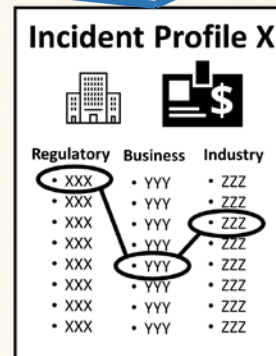


2. Context is added to each issue to capture the bigger picture



3. Incident Profiles are created, and patterns identified

Mesh's AI/ML Analytics Engine

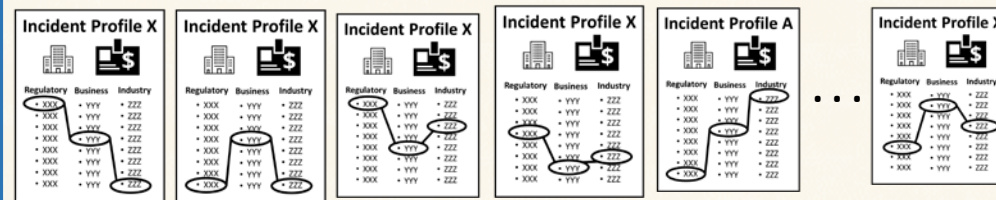


4. Can be combined with internal client data on company and incident

**Client Data**

- Audits
- Inspections
- Contract terms
- Surveys
- Reviews
- Other •

**Mesh's Incident-Intelligence Platform**

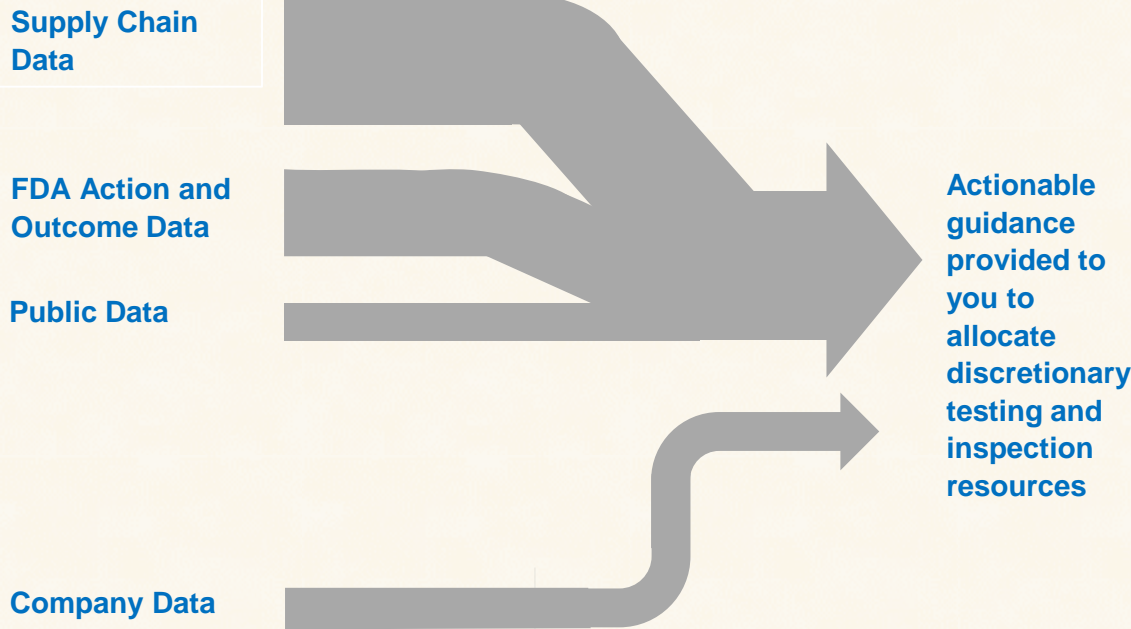


**INCIDENT RISK PREDICTION**

# Installing a smarter food safety and security resource allocation system that learns

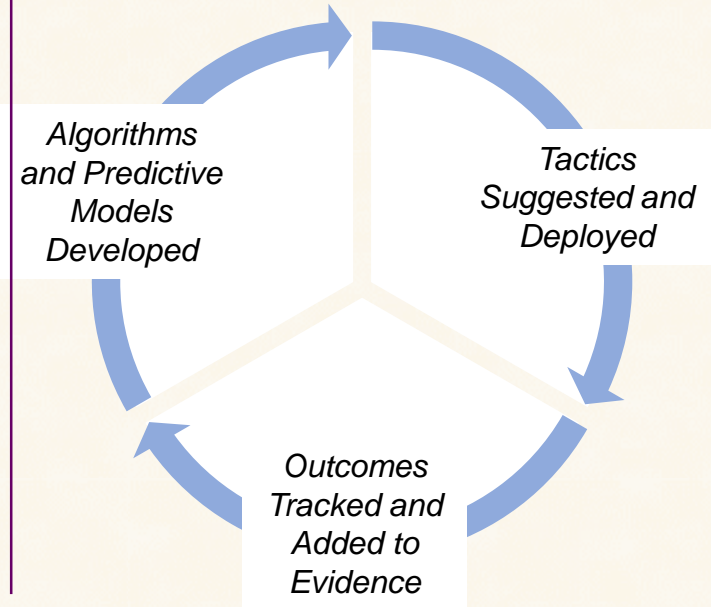
## Feeding Internal Systems With External Risk Signals

*Gaining insight on supplier risks and when linked to internal systems improves allocation of inspection and testing*



## Cycle of Continuous Learning

*Using patterns and outcomes to sharpen predictive accuracy and guidance over time*



Supporting your food safety and security program's Continuous Monitoring and Continuous Improvement efforts

# USING DATA TO IMPROVE COMMERCIAL IMPACT

- Better control of supply chains
- Vendor qualification and Purchase Order controls
- Contract negotiation
- Financial considerations

The better you understanding your risks, the more you can control costs.



# AGENDA

---

- I. Food Safety and Risk
- II. Risk Prediction
- III. Real World Uses of the Data
- IV. Conclusions and Q&A

# CONTINUOUS MONITORING

---

- ✓ Verification and reverification of suppliers
- ✓ Contract renegotiation
- ✓ Supply chain disruptions
- ✓ Audit frequency
- ✓ Audit refinement





# CONTINUOUS IMPROVEMENT

---

- ✓ Acting on product/shipment trends
- ✓ Pre-shipment decisions
- ✓ Better vendor selection
- ✓ Resource allocation
  - Spending time on the right priorities
  - Verification regimes re hazard analysis





# QUESTIONS?

---

**Shub Debgupta**

Mesh Intelligence

shub@meshintel.com

1.202.674.6870

**Benjamin England**

FDAImports.com

blengland@fdaimports.com

1.410.220.2800