

Pilot Projects for Improving Product Tracing along the Food Supply System



Tejas Bhatt, IFT
Jennifer McEntire, Leavitt Partners
Sherri McGarry, FDA



Agenda

- Tejas Bhatt (IFT)
 - Pilot Requirements and Scope
 - Stakeholder Outreach
 - Pilots
 - Cost-Benefit Study
 - Collaboration Platform

- Jennifer McEntire (Leavitt Partners)
 - Key Findings
 - Recommendations to FDA

- Sherri McGarry (FDA)
 - FDA's perspective on the report and next steps

Agenda

- Pilot Requirements and Scope
 - Stakeholder Outreach
 - Pilots
 - Cost-Benefit Study
 - Collaboration Platform
-
- More information at:
 - IFT's Traceability Page: <http://www.ift.org/traceability>
 - FDA's Product Tracing Page: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm>

Pilot Requirements and Scope

- Conduct two food product tracing pilot projects in coordination with the
 - (1) processed food / ingredient sector
 - (2) produce sector
 - Include at least two different types of FDA-regulated foods that have been the subject of significant outbreaks between 2005 and 2010
- Reflect the diversity of the food supply and consider / address confounding factors, such as commingling and trans-shipment
- Develop and demonstrate methods for rapid and effective tracking and tracing of these selected foods that are practical for facilities of varying sizes, including small businesses
- Assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients

Agenda

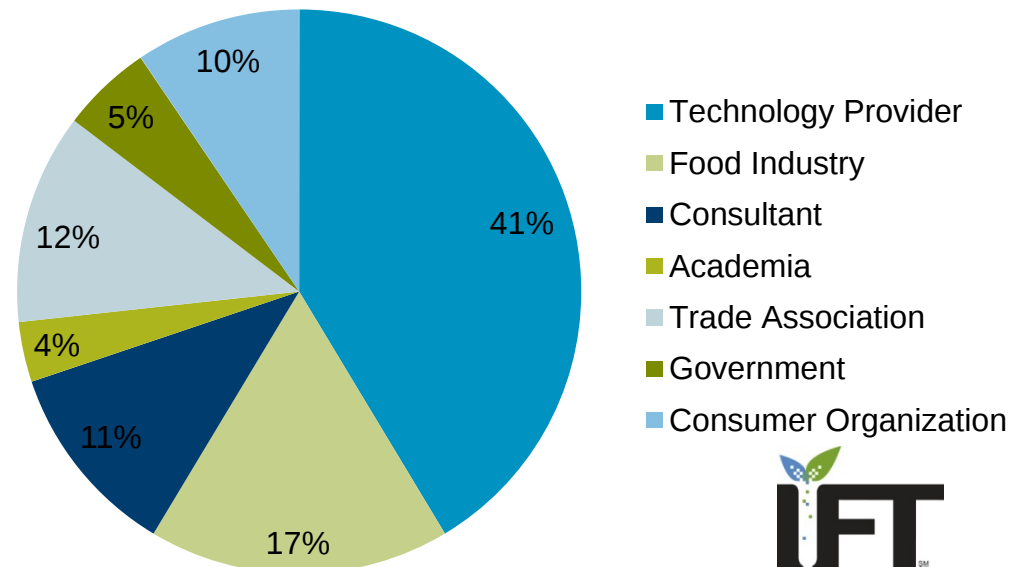
- Pilot Requirements and Scope
- Stakeholder Outreach
- Pilots
- Cost-Benefit Study
- Collaboration Platform

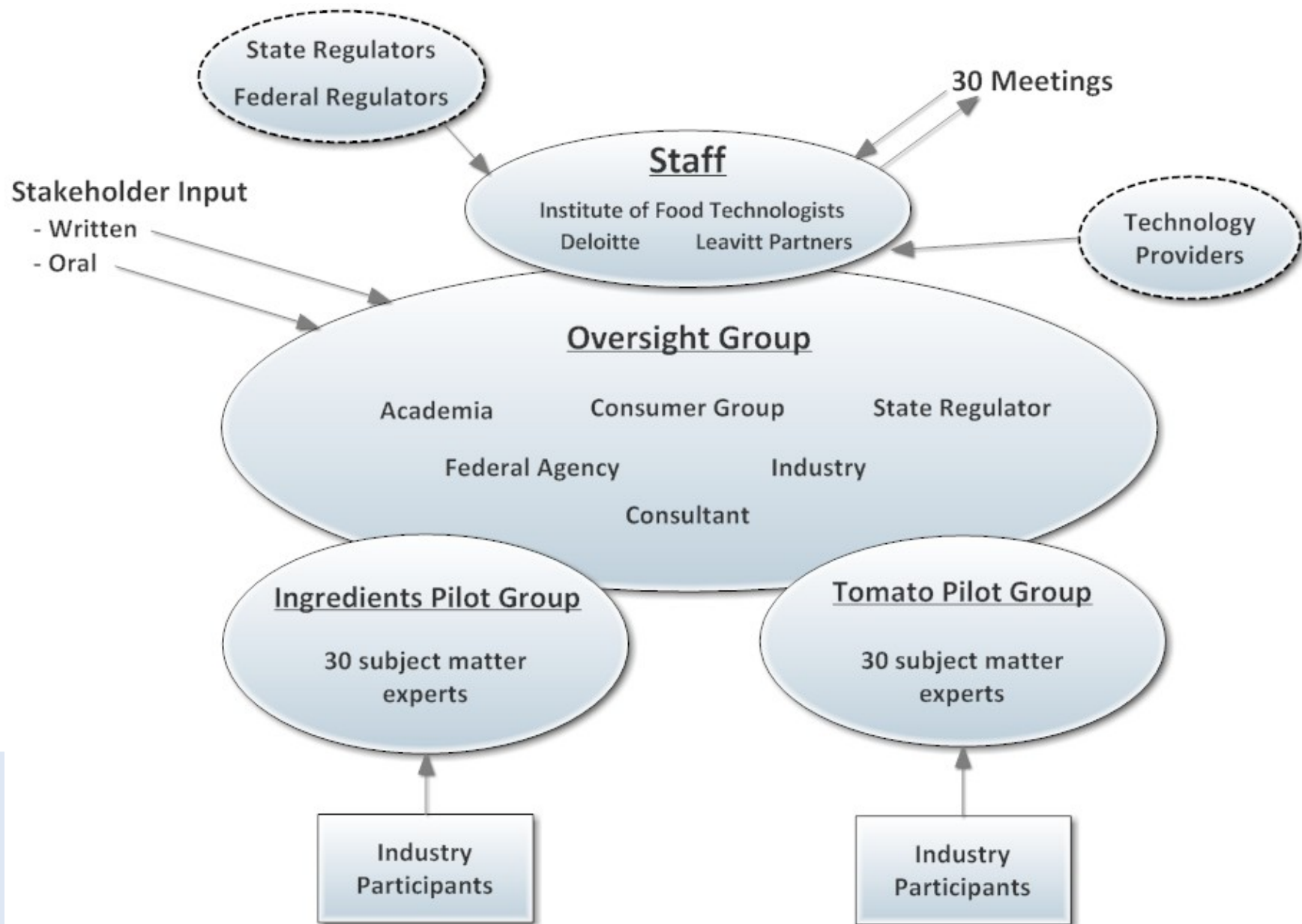
Stakeholder Outreach

- Product tracing contact list of over 750
- Presentations at over 22 national and international venues seeking input
- 41 written and 39 oral comments received

Outreach Efforts	# Individuals / Companies
Presentations at various venues	1108
Food industry	308
Technology Providers	189
Stakeholder Input Sessions	107
Academics (global)	88
Consultants	81
Trade Associations	49
Government representatives (global)	49
Allied organizations	32
Small businesses	25
News media	22
Consumer Groups	13

Stakeholder Input Session Attendee Type





Agenda

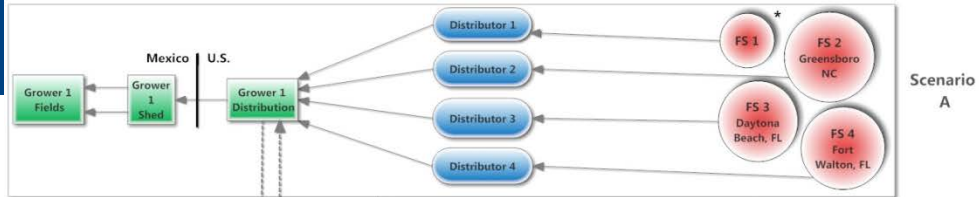
- Pilot Requirements and Scope
- Stakeholder Outreach
- **Pilots**
- Cost-Benefit Study
- Collaboration Platform

Produce Pilot

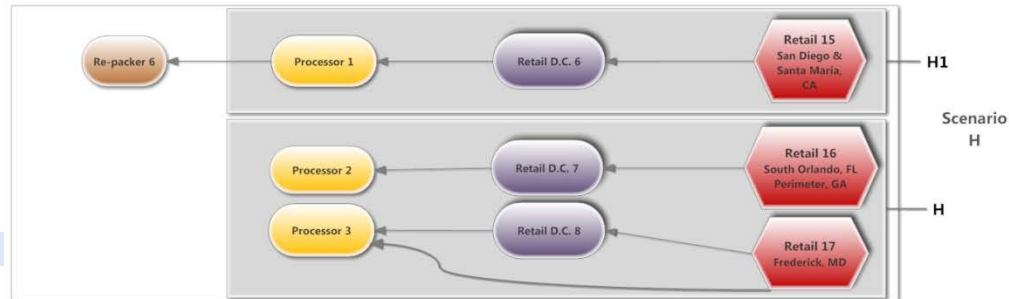
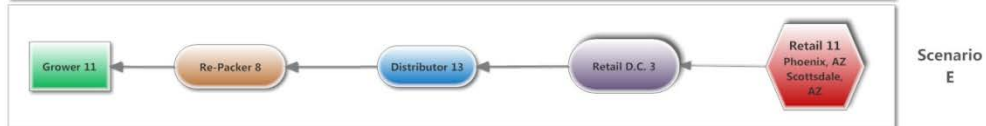
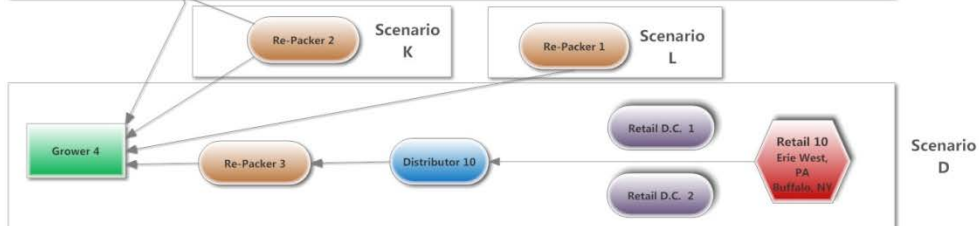
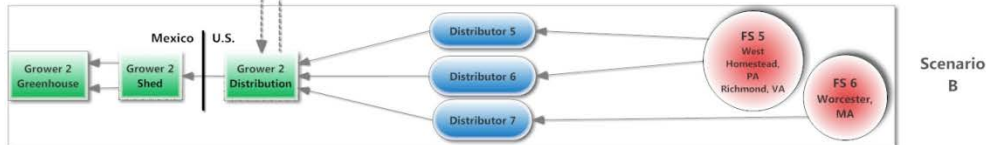
■ Tomatoes

- Associated with significant outbreaks from 2005-2010
- Short shelf-life
- Some commingling
- Participants
 - Growers / packers in US and Mexico
 - Re-packers / processors
 - Distributors & wholesalers
 - Retail
 - Foodservice
- Scenarios
 - Start at retail level where tomatoes may be implicated product





* FS 1 did not receive the product of interest and was able to document this.



Scenario I



Scenario J



Processed Foods / Ingredients Pilot

- “Kung Pao Chicken” style meal
 - Ingredients associated with significant outbreaks from 2005-2010
 - Peanuts
 - Red Pepper
 - Chicken
 - Includes many ingredients, includes USDA-regulated ones
- Participants
 - Importer
 - Ingredient suppliers
 - Manufacturers / co-manufacturers
 - Warehouse and distribution
 - Retailers
 - Additions: Peanut butter, dry kung pao dish
- Scenarios
 - Peanut butter jar tested was violative
 - Shoppers card information
 - Illnesses from frozen/dry product



**Scenario
PA**



Distributor 1

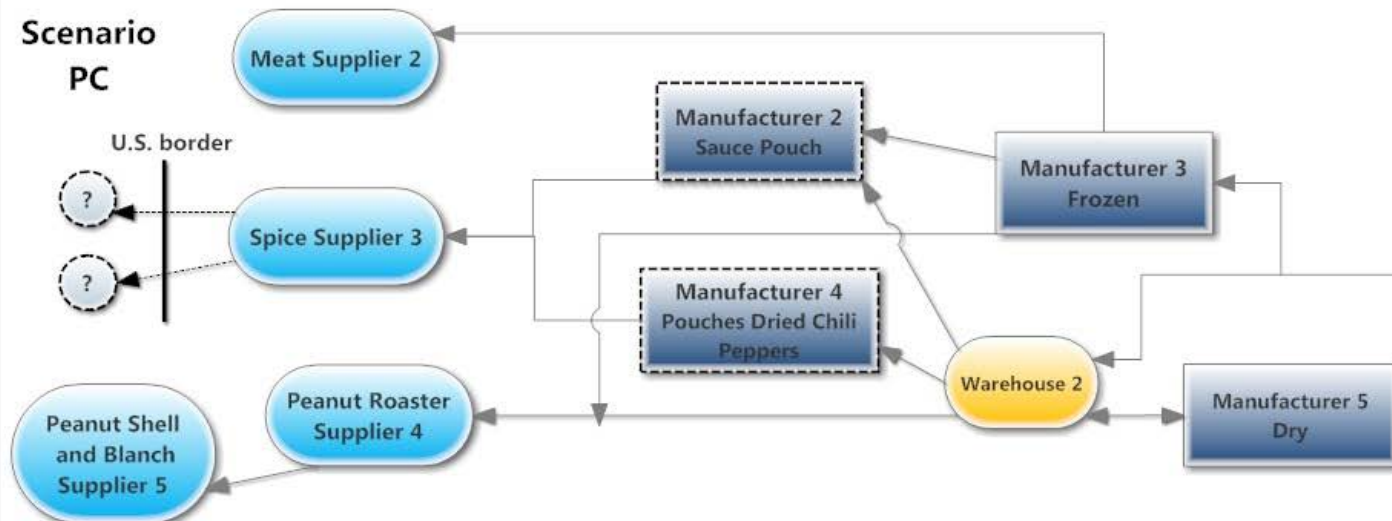
Retail 1
Jamaica Plains, MA
East Northport, NY

Distributor 4

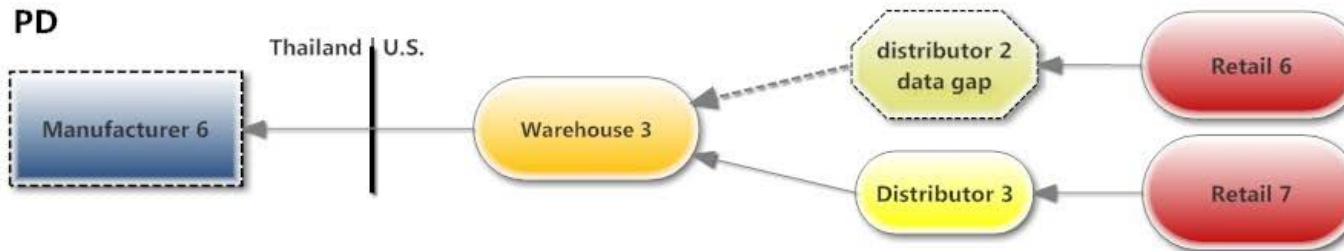
Retail 2
Frederick, MD

**Scenario
PB**

**Scenario
PC**



**Scenario
PD**



Selection of Participants for Pilots

■ Participants

- Volunteers
- Trade associations rallied members
- Major food service supply chain engaged
 - Multiplying effect
- Major manufacturer got supply chain
- Bits and pieces
 - Some volunteers did not have anyone else in their supply chain participating in the pilots

Produce and Processed/ Ingredients Panels

- Included:
 - Pilot participants
 - Industry members not involved in the pilots
 - Subject matter experts
 - Members of the oversight panel
 - Members of the cost panel
- Gave insight and background on supply chains of the two products
- Helped oversee the implementation of the pilots
- Gave input on pilot results and recommendations

Overall Pilot Results

- Clear understanding of terminology is needed
- Template was useful for analyzing data
- Summary documents very useful, with key
- Most KDEs are already captured by the majority of pilot participants
- Capturing more date/time data would be useful
- Activity type/ ID and lot information both useful

Agenda

- Pilot Requirements and Scope
- Stakeholder Outreach
- Pilots
- **Cost-Benefit Study**
- Collaboration Platform

Cost Benefit Evaluation

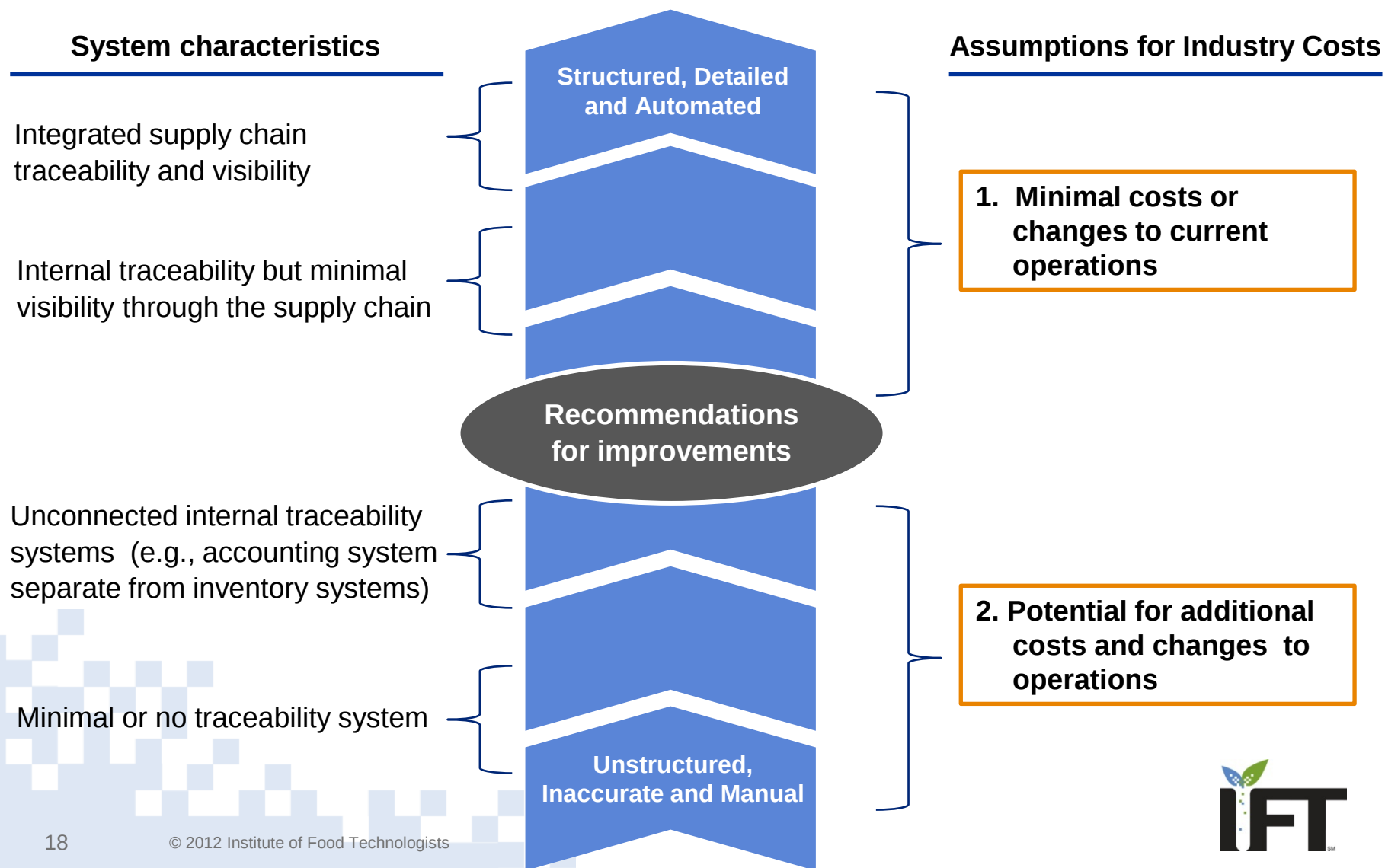
Benefits

- **Public health and social benefits**
 - For example – lives saved, illnesses prevented, gains in productivity
- **FDA operational benefits**
 - responsiveness, reputation, resource allocation
- **Industry benefits**
 - increased brand reputation, increased consumer confidence, improved recall scope, improved supply chain management

Costs

- **FDA operational costs**
 - Analytical and Field FTE's and associated costs; training
 - New System Implementation (Implementation and Maintenance)
 - Compliance
- **Industry implementation costs**
 - Software; Capital expenditures
 - Change to current processes
 - Compliance

Pilot Participants' Product Tracing Maturity Continuum



Cost-Benefit Study Findings

Case Study YR	Max. Illnesses Prevented (%)	Avg. \$ Impact / Day ↓	50% ↓ Traceback Time	Maximum \$ Benefit (100% ↓)
Peppers and tomatoes 08	790 (55)	\$277,275	\$12M	\$14M
Cantaloupe 08	1 (2)	1,053	\$18K	\$18K
Alfalfa sprouts 09	73 (31)	\$23,758	\$806K	\$1.3M
Red & black pepper 10	47 (17)	\$16,496	\$573K	\$841K
Unspecified Mexican 10	2 (3)	\$1,377	\$0	\$36K
Shell eggs 10	120 (3)	\$268,500	\$1.1M	\$2.1M
Ground turkey 11	17 (13)	\$16,016	\$125K	\$304K
Cantaloupe 11	28 (19)	\$153,440	\$384K	\$767K

Agenda

- Pilot Requirements and Scope
- Stakeholder Outreach
- Pilots
- Cost-Benefit Study
- Collaboration Platform

Collaboration Platform

■ Definition

- Data analysis system which could be used by FDA to share and analyze data collected during outbreak investigations
- Collaboration platforms were not used in these pilots directly by food industry participants

■ Selection

- Requested stakeholder input in the fall
- Issued draft request for information in November 2011
- 10 firms selected by a peer-review panel

■ Approach

- Industry data was collected by IFT, then blinded and supplied to the collaboration platform providers
- These collaboration platforms were then used to query the data to look for convergence and conduct tracebacks
- Multiple systems explored – identify key attributes
- Goal was NOT to endorse or select one technology for FDA

Collaboration Platform

■ Assumptions

- FDA is the end-user
- Data NOT shared continually during “normal business”
- Data is “uploaded” as received from industry during outbreak investigations
- Less prescriptive approach to let solutions evolve

■ Limitations

- Technologies were NOT designed for this purpose
- Large disparities in datasets, KDEs and CTEs
- Different approaches to achieve same objectives

Collaboration Platform

- Attributes evaluated
 - Data Import
 - Data Manipulation
 - Visualization methods
 - Data inconsistencies, management of errors
- Non-participants given opportunity for input
 - Tertiary applications to product tracing technologies
 - Environmental monitoring
 - For specific segments of industry
 - Integration of consumers

Thank You!

Tejas Bhatt, IFT
tbhatt@ift.org
<http://www.ift.org>

More information at:
IFT's Traceability Page:
<http://www.ift.org/traceability>

FDA's Product Tracing Page:
<http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm>

