Traceability
From Ugh to Yay
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Agenda for the Day

- Background on tracing- Jennifer
- Working lunch- fill in the blank
- IFT Global Food Traceability Center- Will and Tejas
- Industry Initiatives- Michele and Angela, GS1 US
- Idea exchange- workgroup discussion
- ROI- Michele, Angela and Paul; workgroups
- Summary and next steps- Jennifer

Objectives

- better grasp the various interests and definitions of traceability for retailers;

- understand who within your company needs to participate in the discussion;
  - identify other retail departments to engage in the discussion and identify resources needed

- understand what suppliers are doing now and will be required to do in the future

- identify an approach to evaluate the costs and benefits for retailers

- outline objectives for the FMI and retail food industry

Ground Rules

- Participate in the discussion (in a productive way)
- Feel free to ask questions
- There are no pre-determined outcomes
  - But at the end of the day we need to have next steps
- Follow up with Hilary later if you have additional thoughts, questions or concerns

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Agenda for my talk

- Vote!

- Traceback vs recall

- Tracing in FSMA

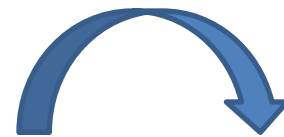- IFT report recommendations and relevance to retailers

Product Tracing in FSMA- Sec 204

- Conduct pilots
  - (A) develop and demonstrate methods for rapid and effective tracking and tracing of foods in a manner that is practicable for facilities of varying sizes, including small businesses;

- 204 (d) Additional Recordkeeping for **High Risk Foods**
  - Relates only to information "reasonably available and appropriate"
  - Science- based
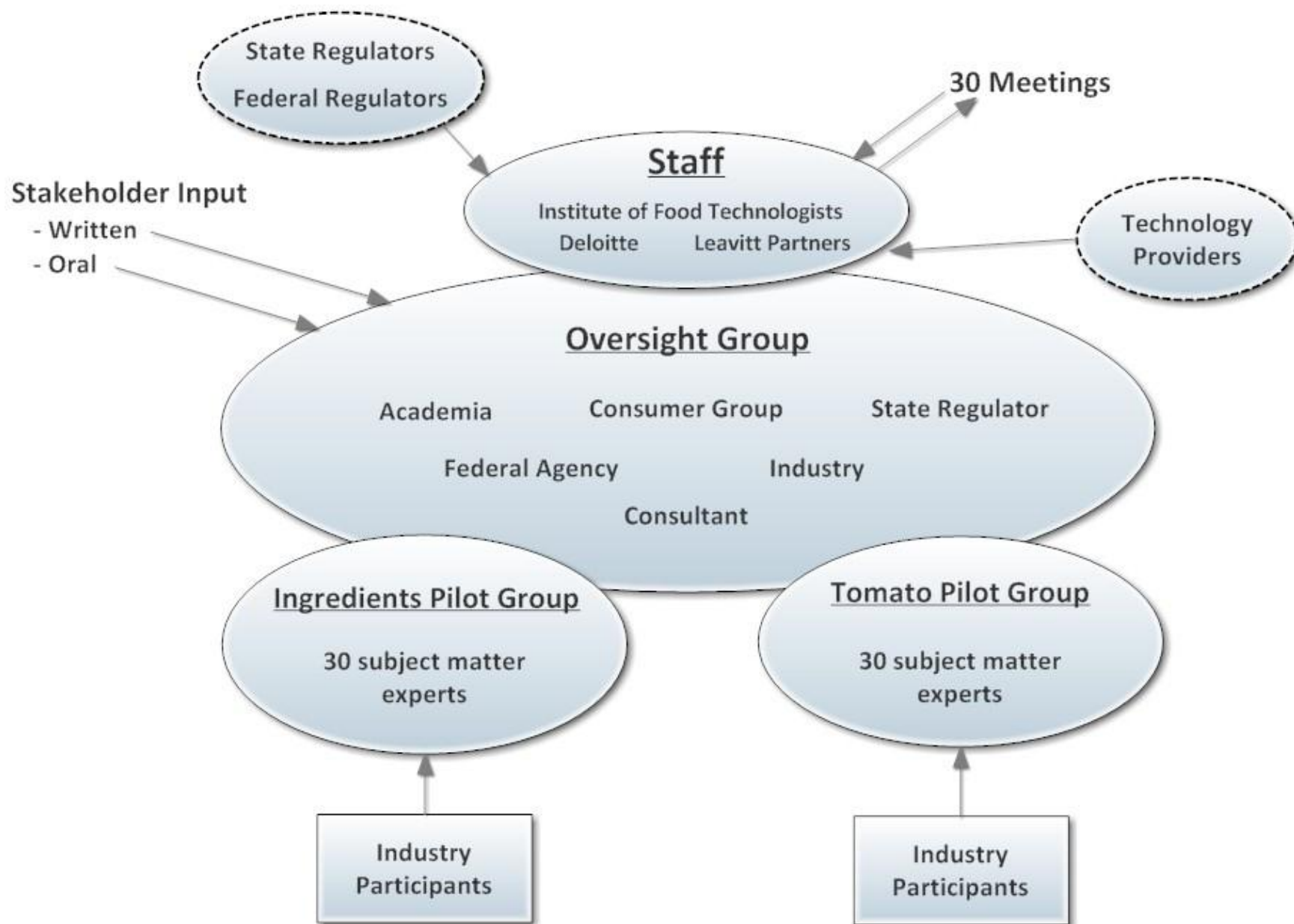 - "Commensurate with the known safety risks of the designated food"

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The Supply Chain

Trace Forward/ Recall:
Where is the food?

| Grower | Processor | Manufacturer | Distributor | Retail store |

Trace Back:
What is causing illness?

IFT Pilot Results

- 3 products
  - Tomatoes
  - Kung pao chicken
  - Peanut butter
- Each "scenario" presented a hypothetical outbreak
- Tracked industry response time and IFT analysis time and numerous other factors

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Pilot Recommendation 1. All food should be traceable

- Controversial!

- FSMA says "only high risk"

- What's "high risk"

- Confusing to have multiple standards or requirements

Rec 2. Recommended CTEs and KDEs

- CTE- Critical Tracking Events are the points in time at a specific location where something changes, that requires you to capture information

- KDE- Key Data Element- the datum that needs to be captured at a particular CTE
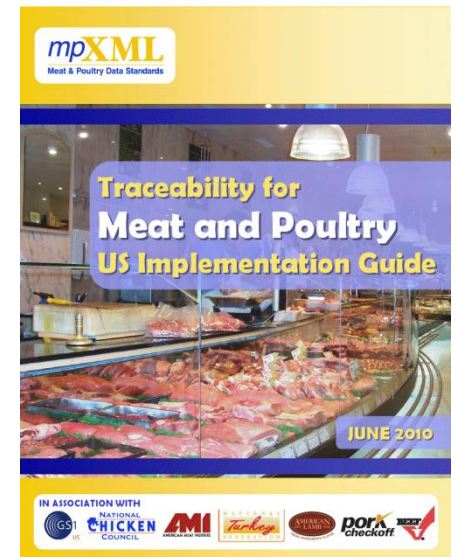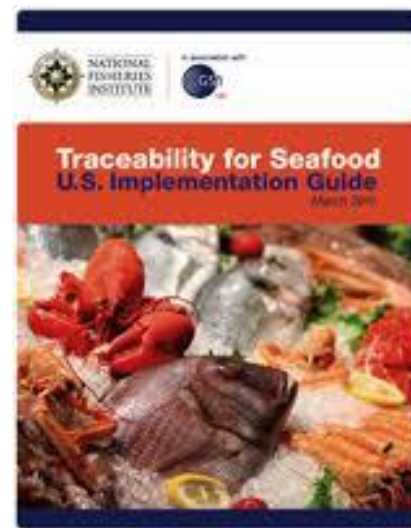
CTEs	Transportation (exchange of goods) - Shipping	Transportation (exchange of goods) - Receiving	Transformation (creation / manipulation of products) – Input	Transformation (creation/manipulation of products) – Output	Depletion (exit from system) – Consumption	Depletion (exit from system) – Disposal
Currently Required KDEs						
Event Owner (firm submitting information)	R	R	R	R	R	R
Date/ Time	R	R	R	R	R	R
Event Location	R	R	R	R	R	R
Trading Partner [1]	R	R	R			
Item (the good)	R	R	R	R	R	R
Lot/Batch/Serial#	BP*	BP*	R	R	BP	BP
Quantity	R	R	R	R	R	R
Unit of Measure	R	R	R	R	R	R
Linking KDEs						
Activity Type (e.g., PO, BOL, Work Order)	C*	C*	R	R		
Activity ID (number associated with PO, BOL, Work Order)	C*	C*	R	R		
Transfer Type [2]	C	C				
Transfer Number [2]	C	C				
Lot/Batch Relevant Date [3]	C	C	C	C	BP	BP
Carrier ID	C	C				
Trailer Number	C	C				

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Pilot Rec. 3. Have a Product Tracing Plan

Traceback	Recall
Conducted by regulators: balance making quick decisions with building a regulatory case	Conducted by industry: protect public health and protect their firm and bottom line
Implicated product not known – reliance on epi	**Specific product(s) known**
Objective: identify points of convergence in supply chain to rule in/out suspects	Objective: remove product from the marketplace
Relies on good recordkeeping by industry	Relies on good recordkeeping by industry

Pilot Rec 4. Support Industry and Seek Input

FDA should encourage and support existing industry-led initiatives for the development of implementation guidelines and should seek targeted stakeholder input via several input mechanisms

FDA is Seeking Input!!

- Public Comments on IFT report are invited until early July (thanks to GMA for requesting an extension on the comment period!)

Pilot Recommendation 5

- FDA should clearly and more consistently articulate and communicate to industry the information needed during a product tracing investigation
  - Industry can help (if the lawyers let them)

Pilot Recommendation 6

- FDA should develop standardized, structured, and electronic mechanisms for industry to provide the Agency CTE and KDE product tracing data when requested during a specific food safety investigation
  - Paper is slow

Pilot Recommendation 7

- FDA should accept CTE and KDE data sent in summary form through standardized and structured reporting mechanisms and initiate investigations based on this data

   need to balance speed vs accuracy

Pilot Recommendation 8

- If available, FDA should request CTE and KDE data for more than one up - one back in the supply chain

    - Totally optional (FSMA specifies FDA can't require more than immediate recipient)
    - Having this information is the exception

Pilot Recommendation 9

FDA should pursue the adoption of a technology platform to allow the Agency to efficiently aggregate and analyze data reported in response to a specific regulatory request

- A "must have" if activity numbers are relied upon
- Should also be available to regulatory counterparts
- Pilot explored 9 systems
  - No endorsement; scores exist

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Pilot Recommendation 10

- Coordinate traceback investigations & develop response protocols between and among state and local health and regulatory agencies

- Use industry Subject Matter Experts (SMEs) to address FDA's general questions about the characteristics of a particular supply chain at the outset of an investigation
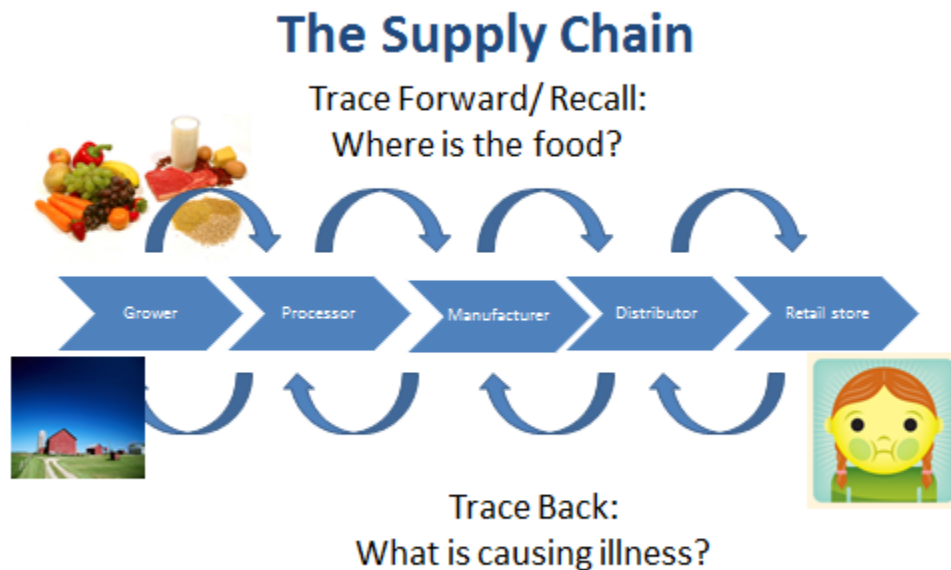
Next Steps for FDA

- Consider public comments (on IFT report, and prior comments)
- Deliver report to Congress with recommendations
- Issue proposed rule

Issue list of high risk foods- as a draft for comment?

- Have 3 public meetings
- Issue proposed rule
- Issue final rule
- Report back to Congress on exclusion of restaurants

Impact on Retail

- Manufacturing- major
- DCs- potentially major
- DC to store- potentially major, in the future

Retail Challenges

- I know what I hear
  - But want you to think about this during the lunch exercise

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Conclusions

- Change is coming
- Regulators and Congress will not accept the status quo
- Traceability is a food safety tool
- Tracking systems need to work
  - Determine the ROI
  - Develop cost effective tools
- Engage with the regulators

Acknowledgments

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- Ben Miller – MN Dept Ag
- Bruce Welt - UFL

Questions?
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