Drum Roll
IFT Tracing Pilot
Key Findings and Recommendations
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Key Findings

- Tedious and difficult to sort through hundreds of pages of documents
  - Mostly pdfs
- Confusion when data definition is lacking
  - Numbers sometimes “mean something”
- Inconsistent item descriptions
  - Does “sauce, Kung Pao” = “Kung Pao sauce”?

Key Findings, cont.

- Wrong or incomplete information cause delays
  - Transposed numbers, wrong dates, BOL without a PO
- Companies operating under multiple names are difficult to identify as sources

Bottom Line

- One up/ one back *should* work
- But the handshake is missing
  - Between companies
  - Sometimes within companies

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

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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

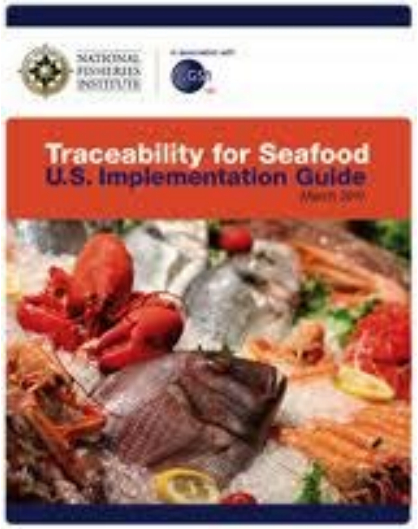
CTEs	Transportation (exchange of goods) - Shipping	Transportation (exchange of goods) - Receiving	Transformation (creation / manipulation of products) – Input	Transformation (creation/manipulation of products) – Output	Depletion (exit from system) – Consumption	Depletion (exit from system) – Disposal
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				

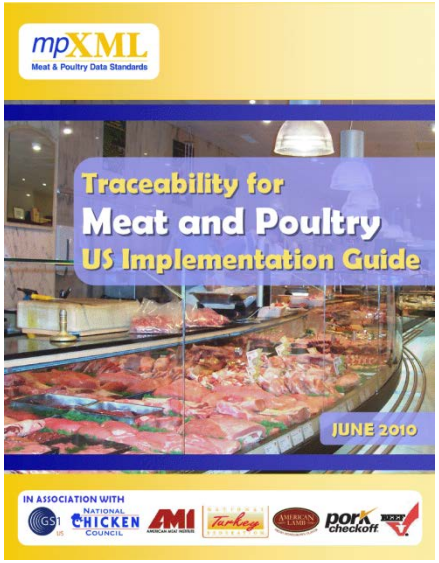
Pilot Rec. 3. Have a Product Tracing Plan

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





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FDA is Seeking Input!!

- Public Comments on IFT report are invited until at least April 5 (GMA has requested an extension)

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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

Pilot Recommendation 10

FDA should coordinate traceback investigations and develop response protocols between and among state and local health and regulatory agencies using existing commissioning and credentialing processes

- FDA should formalize the use of 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

What will change?

- Any additional records/ pieces of data are not known… but IFT recommended some…
- BT Act 2002 1/up/back is still in full effect
  - But clearly inadequate
- FSMA seeks to move beyond the current state of traceability in the US

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Questions?

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