FDA CFSA Workshop
Food Traceability

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http://www.globalfoodtraceability.org

Agenda

- Introductions
  - Who is IFT?
  - What is GFTC?
  - What is traceability?

- FSMA Case Studies
  - Pilots Requirements
  - Pilots Execution
  - Pilots Recommendations
Introduction to Institute of Food Technologists (IFT)

For more than 75 years, the Institute of Food Technologists (IFT) has unlocked the potential of the food science community by creating a dynamic global forum where members from more than 100 countries can share, learn and grow.
IFT Vision

A world where science and innovation are universally accepted as essential to a safe, nutritious and sustainable food supply for everyone.

IFT Mission

To advance the science of food and its application across the global food system.
Introduction to IFT

- More than 18,000 members worldwide
- Members come from industry (80%), academia (15%), and government (5%)
- 18% of IFT members are international & reside in more than 100 countries
Introduction to IFT

- IFT Annual Meeting & Food Expo
- Publications
  - Journal of Food Science
  - Journal of Food Science Education
  - Comprehensive Review in Food Science and Food Safety
  - Food Technology
  - IFT Press Books
  - Newsletters
- Continuing Education & Professional Development
  - Webinars
  - Short courses

Just concluded in Chicago in July!

- 23,500 food professionals from 94 countries
- Over 120 educational sessions
- 1000+ scientific presentations
- 1600 posters
- Record number of booths (2695) at the Expo
1804 Certified Food Scientists in 55 countries

Become a CFS

• Email ifscc@ift.org to learn more
IFT and Food Traceability

Grants and Contracts since 1999
- Governmental
- Academia
- Industry

Research Focus Areas
- Food safety
- Food defense
- Food traceability

Key Partnerships
- FAO, Codex, SENAI
- FDA, USDA, DHS
- GS1US, Underwriters Laboratories
- RTI, Deloitte, Leavitt Partners
- National Center for Food Protection and Defense

IFT and Traceability

<table>
<thead>
<tr>
<th>Year</th>
<th>Traceability Efforts</th>
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</thead>
<tbody>
<tr>
<td>2008</td>
<td>FDA Task Order- Report on “state of the industry”</td>
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<tr>
<td>2009</td>
<td>FDA Task Order- Mock tomato traceback pilot using technology solutions</td>
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<tr>
<td>2010</td>
<td>National Center for Food Protection &amp; Defense (NCFPD) Traceability Project</td>
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<tr>
<td>2011</td>
<td>IFT Traceability Improvement Initiative (TII)</td>
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<tr>
<td>2012</td>
<td>FDA FSMA Product Tracing Pilots</td>
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<td>2013</td>
<td>Global Food Traceability Center</td>
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<tr>
<td>2014</td>
<td>Best Practices in Food Traceability</td>
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<tr>
<td>2015</td>
<td>Business Case for Food Traceability</td>
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<tr>
<td>2016</td>
<td>Food Traceability and its role in Food Protection</td>
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</tbody>
</table>
Introduction to Global Food Traceability Center (GFTC)

Vision

To become the global resource and authoritative voice on food traceability.

Mission

A program to serve the agriculture and food sectors, by providing applied research, objective advice, and practical expertise about data collaboration and food product traceability for business benefit and public good.
Our approach will be to engage stakeholders in the development of solutions, as well as in their delivery.
GFTC Advisory Council Members

- Cargill Inc.
- Centers for Disease Control
- Cornell University
- Eurofins Laboratories Inc.
- FMI Foundation
- Food Fraud initiative
- Global Cold Chain Alliance
- Global Food Safety Partnership (World Bank)
- GS1-US
- International Association for Food Protection
- Intertek Group
- Lowry Solutions
- Lyngsoe Systems A/S
- Mars Inc.
- Food Protection and Defense Institute
- NFI Seafood Industry Research Fund
- Ontario Ministry of Agriculture & Food
- Pepsico
- Produce Marketing Association
- GMA
- Safe Food Canada
- University of Guelph
- USDA
- US Commerce Department
- Wal-Mart Inc.
- Wegmans Food Markets
- Angie Siemens
- Ian Williams
- Robert Gravani
- Douglas Marshall
- Hilary Thesmar
- John Spink
- Lowell Randel
- Amy Evans
- Angela Fernandez
- Tim Jackson
- Arash Eskandari
- Mike Lowry
- Robert Lynn
- David Crean
- Amy Kircher
- Steven Mavity
- Heather Cassidy
- Greg Buckley
- Ed Treacy
- Jennifer McEntire
- Brian Sterling
- Sylvain Charlebois
- Kenneth Petersen
- Corey Wright
- Frank Yiannas
- Gillian Kelleher

GFTC Sponsors

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Introduction to Food Traceability
The Complexity of the Food System

Dig into this pizza and see why food traceability throughout the food system, from farm to fork, is critical to ensuring a safe and abundant food supply.

- **Tomatoes**
  - While the U.S. produces the most tomatoes, Mexico accounts for 71% of tomato imports, and Canada accounts for 27%.

- **Anchovies**
  - 56% of our anchovies are produced in Peru, while pizza anchovies come from Argentina, Croatia, Spain, and Italy.

- **Beef**
  - 2.5 billion pounds of beef were exported this year to top markets like Canada, Japan, Mexico, South Korea, and Hong Kong.

- **Cheese**
  - 14% of the raw buffalo milk used for mozzarella is made in Italy while 86% of buffalo milk is produced in Asia.

- **Mushrooms**
  - China produces 47% of our mushrooms across the globe, followed by the U.S which produces only 11%.

- **Spices**
  - 11.5% of India’s spices are exported to United Arab Emirates, the U.S., the EU, and Malaysia.

- **Peppers**
  - 95% of unprocessed peppers are exported through India, China, and the U.S.

Introduction to Food Traceability

- **Food Protection** • Holistic Approach
- **Food Defense** • Intentional Contamination
- **Food Safety** • Unintentional Contamination
- **Food Sustainability** • Food productivity
- **Food Security** • Food accessibility
Introduction to Food Traceability

- Causality
- Visibility
- Prevention
- Preparedness
- Recovery
- Response
- Trust
- Agility

The Traceability Puzzle

QA/QC Plans
FSMA Rules
HACCP GMPs Food Safety plans
Supply Chain Partnerships
Certification Schemes
Sustainability
Traceability

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Introduction to Food Traceability: Challenges

- Consumers are more vocal
  - Demand for rapid access to reliable and relevant information whenever they need it

Introduction to Food Traceability: Challenges

- Overlapping and conflicting demands from national regulators
Introduction to Food Traceability: Challenges

- Lack of records
  - Data is simply not available, or is difficult to collect

- Is the data
  - Reliable?
  - Relevant?
  - Rapidly accessed?

Globally Aligned

Regionally Relevant
Recent History: Bioterrorism Act of 2002

- Established recordkeeping requirements
  - Manufacturers/processors
    - Record shipment and receipt information
    - Capture incoming lot numbers as possible
    - Link ingredients to finished product to extent practical
  - Non-manufacturers
    - Contact information for who it came from and went to
  - Exemptions at supply chain ends
- "1 up / 1 down" redundant system
- Form of recordkeeping not specified
  - Combinations of paper and electronic records (even within a facility)

Food Safety Modernization Act (FSMA)

- Law passed January 4, 2011
- Most expansive changes since 1938 Act
- Ambitious schedule for increased inspections
- Substantial new regulatory requirements
- Major new program activities for FDA
- Exacting new food import requirements
- Sweeping new enforcement authorities
FSMA: Key Provisions/Sections for Traceability

- Section 103: Hazard Analysis and Risk Based Preventive Controls
- Section 105: Standards for Produce Safety
- Section 106: Protection Against Intentional Adulteration (Food Defense)
- Section 204: Enhancing Tracing and Tracing
- Section 301: Foreign Supplier Verification Program
- Section 302: Voluntary Qualified Importer Program
- Section 303: Import Certifications for Food
- Section 304: Prior Notice of Food Shipments
- Section 307: Accreditation of Third Party Auditors

FSMA: Product Tracing Pilots

- Section 204
  - (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;
  
  - (B) develop and demonstrate appropriate technologies, including technologies existing on the date of enactment of this Act, that enhance the tracking and tracing of food;
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

FSMA Case Studies: Pilots Execution
### 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

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

#### Stakeholder Input Session Attendee Type

- Technology Provider: 41%
- Food Industry: 17%
- Consultant: 11%
- Academia: 4%
- Trade Association: 12%
- Government: 5%
- Consumer Organization: 10%

#### Outreach Efforts

- **Individuals / Companies**: 1108
- **Presentations at various venues**: 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

- Written: 41
- Oral: 39

#### Oversight

- **Staff**
  - Institute of Food Technologists
  - Deloitte
  - Leavitt Partners
- **Technology Providers**: 30 Meetings
- **Academia**
- **Consumer Group**
- **State Regulator**
- **Industry**
- **Consultant**

#### Ingredients Pilot Group

- 30 subject matter experts

#### Tomato Pilot Group

- 30 subject matter experts

#### Industry Participants
Examples of the role of traceability in outbreak investigations

<table>
<thead>
<tr>
<th></th>
<th>Less Complicated Investigations</th>
<th>More Complicated Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiated within one day</td>
<td>Initiated in 1 - 5 days</td>
<td></td>
</tr>
<tr>
<td>Duration of up to 2.5 weeks</td>
<td>2 months or more in duration</td>
<td></td>
</tr>
<tr>
<td>4 - 20 hours required</td>
<td>8 - 240 hours required</td>
<td></td>
</tr>
<tr>
<td>Clear epidemiological link</td>
<td>Poor consumer recall; multiple potential items</td>
<td></td>
</tr>
<tr>
<td>Longer shelf life product</td>
<td>Shorter shelf life product</td>
<td></td>
</tr>
<tr>
<td>Label/bar code information captured*</td>
<td>No label or bar code; reuse of boxes*</td>
<td></td>
</tr>
<tr>
<td>Records kept on-site</td>
<td>Records stored off-site</td>
<td></td>
</tr>
<tr>
<td>Legible, English records*</td>
<td>Records illegible, not English*</td>
<td></td>
</tr>
<tr>
<td>Good internal tracing*</td>
<td>No record of ingredients used in finished products or record of cases shipped within the distribution center*</td>
<td></td>
</tr>
<tr>
<td>Shipping/receiving information captured*</td>
<td>Invoices do not reflect change in orders; use of undocumented “fill-in” product*</td>
<td></td>
</tr>
<tr>
<td>*Electronic records</td>
<td>Paper records; errors in data entry*</td>
<td></td>
</tr>
</tbody>
</table>

* were assessed in the pilots.

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
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

- Factors Evaluated
  - Long shelf life product
  - Impact of shoppers card information
  - Influence of frozen and dried product
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

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
FSMA Case Studies: Pilots Recommendations

Recommendation 1

Overarching

- FDA should establish a uniform set of recordkeeping requirements for all FDA-regulated foods
  - No exemptions based on risk classification
  - Guidance documents need to be created by FDA defining these requirements
Pilot Recommendation 2

- FDA should require all firms in the supply chain to identify and maintain records for all Critical Tracking Events (CTEs) and corresponding Key Data Elements (KDEs) as defined by FDA
  - Should be based on input from the food industry

Pilot Recommendation 3

- FDA should require each member of the food supply chain to develop, document, and exercise a product tracing plan

*Sec 103- FDA can require a recall plan
Pilot Recommendation 4

- 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.

Pilot Recommendation 5

- FDA should clearly and more consistently articulate and communicate to industry the information needed during a product tracing investigation.
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
  - Reliability, relevance, rapid access
Pilot Recommendation 8

- If available, FDA should request CTE and KDE data for more than one up - one back in the supply chain
  - 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
  - The technology platform should also be available to regulatory counterparts
  - Pilot explored 9 such products, 1 of which is already used by CDC
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

Next Steps for FSMA Food Traceability (Section 204)

- FDA reports to Congress
  - Will include IFT’s Report

- FDA will establish list of high risk foods
  - Proposed rule will only apply to high risk foods

- Proposed Rule for Additional Recordkeeping Requirements
  - Will hold 3 public meetings for input

- Final Rule
  - Waiting for proposed rule to be published

- FDA will issue guidance documents
  - Probably tiered for very small to large firms
Thank you!

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