Evaluating the Food Safety Modernization Act (FSMA) Proposed Rule for Food Traceability

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Rebecca Goldberg, Associate Chief Counsel, FDA Office of the Chief Counsel
Bryan Hitchcock, Senior Director, Food Chain & Global Food Traceability Center, The Institute of Food Technologists (IFT)

Moderated by Allen Sayler, Senior Director of Food Consulting Services, EAS Consulting Group
Does Enhanced Traceability and Recordkeeping Improve Food Safety?

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June 2, 2020

Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety

- Smarter tools, such as root cause analyses
- Predictive analytics - use data to anticipate the likelihood of contamination.
- Virtual or remote inspections
- Collaboration between government and industry
- Partnerships between the FDA, local and state regulatory and public health counterparts
- Strengthen relationships between federal partners – CDC, USDA, OSHA
- Emerging technologies, such as blockchain, make it easier to track and trace products through the supply chain – from the time that they are grown or manufactured, until purchased by a consumer, and back through the supply chain

GOAL - Digitized food system is likely to be a stronger, more agile.
(c) Product Tracing System.--The Secretary, in consultation with the Secretary of Agriculture, shall, as appropriate, establish within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States. Prior to the establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.

(d) Additional Recordkeeping Requirements for High Risk Foods.

At the time the Secretary promulgates the final rules under paragraph (1), the Secretary shall publish the list of the foods designated under subparagraph (A) as high-risk foods on the Internet website of the Food and Drug Administration. The Secretary may update the list to designate new high-risk foods and to remove foods that are no longer deemed to be high-risk foods, provided that each such update to the list is consistent with the requirements of this subsection and notice of such update is published in the Federal Register.
Seven (7) Final FSMA & Two (2) Proposed Rules

1. Human Food preventive controls
2. Animal Feed preventative controls
3. Produce rules – will set standards for farm growing practices
4. Foreign Supplier Verification Proposed Rule – importer accountability program to ensure imported foods are produced under the same standards/level of protection, as our new preventative control of produce standards.
5. Accredited Third Party Certification of Foreign Suppliers.
6. Safe Food Transport rules
7. Mitigation Strategies to Prevent the Intentional Adulteration of Food
8. Private Laboratory Certification (Proposed)
9. Traceability Recordkeeping (Proposed)
Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report

Final submission in August 2012 by:

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IFT STUDY RECOMMENDATIONS

Tracing & Tracking

Mid-March 2013 with 10 recommendations:

1. FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.

2. FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of critical tracking events (CTEs) and key data elements (KDEs) as determined by FDA.

3. Each member of the food supply chain should be required to develop, document, and exercise a product tracing plan.
IFT STUDY RECOMMENDATIONS

Tracing & Tracking

4. FDA should encourage current industry-led initiatives and issue an Advance Notice of Proposed Rulemaking or use other similar mechanisms to seek stakeholder input.

5. FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.

6. FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.

7. FDA should accept summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.
IFT STUDY RECOMMENDATIONS

Tracing & Tracking

8. If available, FDA should request more than one level of tracing data.

9. FDA should consider adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.

10. FDA should coordinate traceback investigations and develop response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.
# IFT Traceability Report – Table 51
## Summary of Recommendations

<table>
<thead>
<tr>
<th>Steps</th>
<th>Improve Accuracy</th>
<th>Improve Speed</th>
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<tr>
<td>Establish Uniform Recordkeeping Requirements</td>
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<td>Maintain CTEs and KDEs</td>
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<td>Require Industry “Traceback Response Plans”</td>
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<td>Support Industry-Led Initiatives</td>
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<tr>
<td>Communicate Needed Information</td>
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<td>Develop Standardized, Electronic Reporting Templates</td>
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<td>Accept CTEs and KDEs in Summary Form</td>
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<tr>
<td>Request more than One up – back</td>
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<tr>
<td>Use Technology to Share and Analyze Data</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Coordinate with State and Local Counterparts, and Use Industry SMEs as appropriate</td>
<td>X</td>
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Food Traceability Proposed Rule - Requirements for Additional Traceability Records for Certain Foods

• Proposed Rule (55 pages) published in the Federal Register on September 21, 2020
• Open for comments until January 21, 2021
• FDA Deputy Commissioner Frank Yiannas said untangling the mess of shipping and sales records that currently hampers outbreak investigations is something everyone can understand and is driving the transition from paper-based recordkeeping to electronic records.
Why is traceability important?

• When a foodborne illness outbreak occurs, need to quickly identify and remove contaminated food from market to avoid additional illnesses/deaths

• Need accurate information on the food to trace it back through the supply chain to identify the source and also forward to determine how the food was distributed
### Current State

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<td>Quality: Tomato Large</td>
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<td>Quality: Tomato 4X6</td>
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*Note:* The images contain additional documents with various details such as distribution information, product specifications, and communication details.
What does the Food Traceability proposed rule do?

- Requires covered persons to maintain records for foods on the Food Traceability List that will support more efficient and accurate traceability of potentially contaminated food
Background

• **Proposed Rule:** Published September 23, 2020

• **Virtual Public Meetings:** Nov. 6, Nov. 18, Dec. 2, 2020

• **Public Comment period ended:** February 22, 2021

• **Final Rule:** Under consent decree, FDA must submit a final rule to the Office of the Federal Register by November 7, 2022
Benefits of the Food Traceability Proposed Rule

• Fewer foodborne illnesses/deaths
  o Faster identification of source of contamination
  o Rapid removal of contaminated food from market

• Limit the scope of recalls

• Harmonized information
  o Establish linkages along supply chain more quickly

• Aligns with current industry approaches

• Enhances ability to conduct root cause investigations to identify and apply lessons learned from outbreaks
Key Concepts of the Proposed Rule

- Touches the whole supply chain from farms and facilities to retail food establishments
- Includes both foreign and domestic entities
- Only applies to certain foods
- Some exemptions and partial exemptions
- Co-proposal on Retail Food Establishments
Proposed Requirements

Critical Tracking Events
Growing, receiving, transforming, creating, and shipping are Critical Tracking Events (CTEs) for which records would be required.

Key Data Elements
Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

The KDEs required would vary depending on the CTE that is being performed.
The records required at each CTE would need to contain and link the traceability lot code of the food to the relevant KDEs.
Review of Proposed Rule Key Concepts

• Traceability Lot Codes should carry through the supply chain and can only be established and assigned when origination, transformation, or creation occurs

• All proposed KDEs would be required to be linked to the TLC

• Where possible, firms can reuse KDEs provided by the immediate previous source to meet proposed requirements (e.g., traceability product identifiers, etc.)

• Traceability Program Records would be required to explain terminology used in a firm’s internal traceability system that may differ from the terminology of the proposed rule
Review of Proposed Rule Key Concepts

• Records required by the rule would have to be provided to FDA within 24 hours of the record request regardless of where records are stored
  — Records can be maintained by a 3rd party (or other firm in the supply chain)

• Any firm can be a receiver; first receiver is more specific
  — Dependent on the structure of a product’s supply chain
  — First receiver is the first non-farm that purchases and takes physical possession; created foods don’t have first receivers

• Goal of the proposed rule is to ensure KDEs (especially TLC) can be maintained across the supply chain for more efficient and effective tracing while providing firms flexibility within their existing tracing systems
Example: Critical Tracking Events (CTEs) for Fresh-Cut Romaine Supply Chain
§1.1455: Records Maintenance and Availability

Legible records maintained as either original paper records, electronic records, or true copies and stored to prevent deterioration or loss.

In general records must be kept for 2 years from the date you created the record.

Records would have to be made available to FDA as soon as possible, but no later than 24 hours after a request is made.

If requested to assist FDA during an outbreak or other threat to public health, records would need to be provided to FDA in an electronic sortable spreadsheet.
# Exemptions

## Statutory Exemptions

- Farms selling food directly to consumers
- Food produced/packaged/labeled on farm

## Statutory Partial Exemptions

- Certain commingled RACs (not fruits & vegetables)
- Fishing vessels
- Farm-to-school/institution programs

## Additional Proposed Exemptions

- Very small farms
- Produce and shell eggs that receive certain processing
- Produce on FDA’s “rarely consumed raw” list
- Transporters of food
- Non-profits, personal consumption

## Additional Proposed Partial Exemptions

- Retail food establishments receiving food directly from a farm (expanded from “grocery stores”)

In addition, traceability records would not be required after a kill step is applied. Record of kill step application would have to be maintained by the person who applied the kill step.
§§ 1.1360 – 1.1400: Procedures for Modified Requirements and Exemptions

- Modified requirements or an exemption
- For a food or type of entity
- If FDA determines that application of the requirements is not necessary to protect the public health
- FDA will consider whether to modify requirements or grant exemption on our initiative or
- Citizen petition by any interested party
§§ 1.1405 – 1.1450: Waivers

• Waiver for one or more of the requirements in the rule
  — For an individual entity or type of entity
  — If we determine that application of the requirements would result in an economic hardship due to the unique circumstances of the individual entity or type of entity; and
  — The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate an outbreak or address credible threats of serious adverse health consequences or death; and
  — The waiver will not otherwise be contrary to the public interest
  — FDA will consider whether to issue a waiver on our initiative or
    o Written request for an individual entity
    o Citizen petition for a type of entity
Proposed Requirements

What happens if I fail to comply with the requirements?

• Violation of the recordkeeping requirements is a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.

• An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements have not been complied with regarding such article.
Compliance dates

• If finalized, the rule would become effective 60 days after it is published in the Federal Register.

• Compliance date for *all covered entities* would be two years from the effective date of the final regulation.
# Food Traceability List

<table>
<thead>
<tr>
<th>Food Traceability List</th>
<th>Food Traceability List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheeses, other than hard cheeses</td>
<td>Sprouts (fresh)</td>
</tr>
<tr>
<td>Shell eggs</td>
<td>Tomatoes (fresh)</td>
</tr>
<tr>
<td>Nut butter</td>
<td>Tropical tree fruits (fresh)</td>
</tr>
<tr>
<td>Cucumbers (fresh)</td>
<td>Fruits and Vegetables (fresh-cut)</td>
</tr>
<tr>
<td>Herbs (fresh)</td>
<td>Finfish, including smoked finfish</td>
</tr>
<tr>
<td>Leafy greens (fresh), including fresh-cut leafy greens</td>
<td>Crustaceans</td>
</tr>
<tr>
<td>Melons (fresh)</td>
<td>Mollusks, bivalves</td>
</tr>
<tr>
<td>Peppers (fresh)</td>
<td>Ready-to-eat deli salads</td>
</tr>
</tbody>
</table>
Food Traceability List

Foods for which traceability records will be required

• Under the proposed rule, foods designated as high-risk are listed on the Food Traceability List (FTL).
• Foods for which traceability records will be required
• To determine which foods should be included on the FTL, FDA developed a Risk-Ranking Model for Food Tracing
• The model scores commodity-hazard pairs according to data and information relevant to FSMA requirements
FSMA Requirements
Section 204(d)(2)(A) (21 U.S. Code § 2223(d)(2)(A))

Designation of high-risk foods shall be based on

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.
A Systematic, Transparent, and Participatory Process

- Project Advisory Group
- Draft Approach
- Public Comment
- Collect Data
- Develop Model
- Internal Review
- External Peer Reviews (Model + Data)
- Revise Model Update Data Quality Control
- Review & Clearance
- Report

www.fda.gov
Data Sources

• Published literature
• Government surveys and investigations
• Expert elicitations
• Data calls via Federal Register Notice
  • data and information provided by stakeholders
Overall Approach to Designation of the List

• Create a data-driven risk-ranking model
• Score food-hazard pairs based on risk factors specified in FSMA sec. 204(d)(2)(A)
• Aggregate scores appropriately to create ranked list of foods (commodities and commodity categories)

• Designate Food Traceability List
RRM-FT Scoring and Ranking Process

Data → Criteria → Commodity-Hazard Pairs → Ranked List of Commodity-Hazard Pairs → Commodities → Ranked List of Commodities

All relevant commodity-hazard pairs scored:
- 60 hazards
- 210 commodities
- 370 pairs
- 1000 references
- > 10,000 data points

C₂H₅ RISK SCORE

C₆ RISK SCORE
The FDA does not anticipate updates to the list to happen very often.

FDA will periodically review relevant data and information to determine if we need to update the FTL.

If we determine we should update the FTL, we will do so via a notice in the Federal Register providing the public with an opportunity to comment.

Any additions to the list would become effective one year after the date we publish any final changes to the FTL.
• Three Public Meeting recordings and transcripts available
• Food Traceability proposed rule webpages
  • Additional Information:
    • NEW: Frequently Asked Questions about the Food Traceability Proposed Rule
    • Food Traceability Proposed Rule At-A-Glance
    • Food Traceability Proposed Rule Exemptions At-A-Glance
    • Food Traceability List
    • Risk Ranking Model for Food Tracing tool
    • Which Key Data Elements Would Apply to Me?
    • Who is Subject to the Rule Flowchart
    • Pre-recorded Webinar to Discuss Food Traceability Proposed Rule
    • Supply Chain Examples
    • First Receiver Examples
    • Creation and Transformation
    • Webinar/video
• Additional questions related to this rule should be sent to the FSMA Technical Assistance Network
• Meeting requests related to this rule should be submitted to FSMA204Traceability@fda.hhs.gov
• Comments should be submitted to docket FDA-2014-N-0053 on regulations.gov
FDA’s Proposed Rule for Food Traceability: Concerns for Small Farm and Food Businesses

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Core Element 1 – Tech Enabled Traceability

• Who will/should the costs of these new systems, and what are the impacts on smaller operations?
• The plan notes FDA will identify “low to no cost solutions ... that enable producers of all sizes to participate” but but how will it identify these new models?
• Will there be cost sharing, and will it be sufficient?
• Even if there is funding available, how will issues of internet access and other barriers to technology be addressed, particularly in the agricultural sector?
Overarching Concerns

• Timing
• Clarity
• Enforcement
Process Concerns

• Given the magnitude of change required for some producers, more time is needed to submit comments

• Small farms may have assumed this proposal didn’t apply to them and consequently failed to submit comments that could inform the rulemaking process
General Concerns

• FSMA specified that FDA could not require specific technologies or practices
• FDA’s “encouragement” of electronic recordkeeping will require significant investment and training for smaller entities that historically have kept paper records
• First receivers of food (other small entities that aren’t farms) may be ill equipped to maintain records and, in turn, require it of the small farms
• FDA hasn’t completed a full examination of the impacts of the proposed rule on small entities
General Concerns, cont’d.

• FDA’s proposed food traceability list includes foods that are not inherently dangerous
• The proposed rule’s packaging requirements to maintain integrity may be overly expensive for small producers and some question the basis
• Exemption for small retail food establishments with 10 employees or less may not adequately protect the food supply chain or may not exempt other RFEs that would
• FDA needs to ensure adequate funding for education, training, and technological improvements
• How will questions about interpretation during enforcement be resolved fairly and consistently?
Thank you!

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Advancing Traceability Science and Practice Since 2008

About IFT & GFTC
- Who we are
- What we do
- How we work

Standards
- Unique Identification
- Interoperability
- Data Quality & Privacy

Sector Collaborations
- Industry Specific Standards
- Best Practices

Training and Development

Tools and Resources
- Pilots
- Best Practices
- Financial Analysis
- GitHub Documentation

Technology
- Software & Hardware
- Data Capture
- Sensors
The technology-agnostic, authoritative voice on food traceability.

- Standard development and extension for multiple use cases (co-convener of the Global Dialogue on Seafood Traceability, ‘GDST’)
- Best practices and guidance documentation
- Implementation and Compliance Tools
- Technical convenings and pilots
- Education, training and workshops
- Marketing, outreach, and communication
Collaborative, business-led, standard development

GDST Standard 1.0

- Released March 2020
- Adopted by 48 companies around the globe, implementation underway
- Endorsed by 20+ solution providers and 10+ NGOs
- Versions appropriate for wild caught and farmed varieties of seafood
- Facilitates IUU enforcement and Import Regulatory Compliance

| GDST 1.0 Standards and Materials

Background on GDST 1.0 Materials

The GDST 1.0 materials are the product of the GDST Secretariat and reflect extensive dialogue with GDST members and external experts. These documents constitute the full set of GDST 1.0 materials. The packet, as of February 2020, includes materials listed in the table below. If there are any questions or concerns, do not hesitate to contact the GDST Secretariat at info@traceability-dialogue.org.

To download the materials, please click the document titles in the table below.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Contents</th>
<th>Translations</th>
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<tbody>
<tr>
<td>Guide to the GDST 1.0 Materials</td>
<td>Overview of GDST 1.0 packet contents + “How to use these documents”</td>
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<tr>
<td>Executive Summary</td>
<td>A two-page description of GDST 1.0</td>
<td>Chinese, Japanese, Spanish, French</td>
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<tr>
<td>Core Normative Standards</td>
<td>The GDST 1.0 standards themselves</td>
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<td>e-spreadsheet of Appendices to Core Normative Standards</td>
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<tr>
<td>Technical Implementation Guidance</td>
<td>Additional technical materials to facilitate implementation</td>
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Leafy Greens Traceability Pilot

- 6 association partnership with FDA participation
- 3 farm to consumer produce (romaine focused) pilots
- Teams of industry experts
- Completed December 2020

- Learn more at www.ift.org/leafygreens
Overview of the Tool

• Provides ROI insights
  • Multi-factor inputs (e.g., supply chain role, baseline system)
  • Investment and expected return outputs

• More info: www.ift.org/gftc
Other Tools and Resources

Small-scale data capture app (open source)

Nemo United States

Welcome back Captain!

What would you like to add?

What have you caught?

Atlantic Cod

Blue Crab (Atlantic)

Dolphinfish (Mahi Mahi)

Potato Grouper

Standards Facilitation Tool

- Streamlines pilot methods for global scale
- Actionable technical outputs for companies
Thank you!

Questions and Comments?

Bryan Hitchcock
bhitchcock@ift.org