PARTNERSHIP FOR FOOD TRACEABILITY

FSMA 204 Pilot Program Invitation

Industry Data Sharing via Electronic Sortable Spreadsheet

Industry Testing Electronic Sortable Spreadsheets (ESS)

Based on the requirement to share an electronic sortable spreadsheet (ESS) with FDA within 24 hours of a request during an investigation

Sponsored by the Partnership for Food Traceability

Purpose

The Partnership for Food Traceability (PFT) is inviting food supply chain stakeholders to participate in a collaborative pilot program with two primary objectives:

1. Test the ability of industry stakeholders to complete an electronic sortable spreadsheet (ESS) covering Critical Tracking Events (CTEs) and Key Data Elements (KDEs) across the supply chain. This includes activities such as initial packing, transforming, receiving, and shipping Food Traceability List (FTL) food, as well as Congress-specified scenarios including food waste, food recovery, intra-company transfers, and customer returns of FTL food.
2. Optionally, share an ESS with the PFT Pilot Committee Working Group for impartial review and feedback. Participants can choose to provide the data in machine-readable formats as long as an ESS is submitted as well. Feedback provided is educational in nature and does not constitute a determination of compliance with the Food Traceability Rule.

Background

The Food Traceability Rule (FTR) establishes recordkeeping requirements for foods on the Food Traceability List (FTL), including the capture of Key Data Elements (KDEs) at Critical Tracking Events (CTEs). The revised compliance date is July 20, 2028. The rule offers flexibility in how KDEs are received, stored, and shared with trading partners, but

when conducting a traceback investigation for a foodborne outbreak, FDA may request KDEs in an electronic sortable spreadsheet (ESS) format.

Current business practices across the supply chain may not include all required KDEs as part of routine transactions, and many companies are still configuring how KDEs will be created, maintained, and shared. This pilot gives companies the opportunity to test their ability to populate an ESS using their current data systems. If they choose, participating companies will also be able to evaluate their effectiveness in sharing data, leveraging the PFT Pilot Committee Working Group as a model sharing entity. Learnings from this pilot will be communicated to FDA to enhance understanding of real-world FTR implementation challenges.

Pilot Goals

1. **Document current-state practices** for sharing Key Data Elements (KDEs) at Critical Tracking Events (CTEs) using an ESS.
2. **Test and evaluate the success** of populating KDEs into an electronic sortable spreadsheet (ESS) and sharing (optional) with a model organization, the PFT Pilot Committee Working Group.
3. **Identify implementation requirements,** including system modifications, trading partner coordination (if applicable), process changes, time, and cost (labor and otherwise).
4. **Capture lessons learned** regarding workflow, cost considerations, and operational feasibility.
5. **Provide actionable recommendations** for industry stakeholders and the FDA based on real-world implementation experience.

Pilot Scope and Example Methodologies

Participants will define their own pilot scope based on CTEs and associated KDEs present in their operations (review Appendix A for more information). Participants are encouraged to consider using best practices in data structuring outlined by GS1 and PTI to populate FDA's electronic sortable spreadsheet (ESS) or other type of electronic sortable spreadsheet. Pilot participants have the option to also provide information in machine-readable formats, like JSON and EPCIS, as long as an ESS is submitted as well.

Who Should Participate

We encourage participation from all supply chain stakeholders that have at least one CTE:

- **Harvesters, coolers, and initial packers of produce, seafood, and shell eggs** covered by the Rule
- **First land-based receivers of seafood** covered by the Rule
- **Food manufacturers, processors,** and any industry stakeholders transforming or repacking FTL food
- **Distributors and wholesalers with receiving and/or shipping CTEs**
- **Any industry stakeholder conducting recovery, customer returns, food waste, intra-company shipments of FTL food**
- **Retailers and restaurants** implementing KDE receipt and recordkeeping processes
- **Technology and solution providers** offering tools for KDE management and data exchange

Why Participate?

Across the industry, organizations have developed significant pilot learnings, but there is no centralized mechanism to collect those learnings and deliver them to FDA. By participating in this pilot program, you will:

- Optionally, receive feedback from PFT Pilot Committee Working Group on your submitted ESS
- Help inform industry and FDA's continued implementation of the Food Traceability Rule. Learnings may be leveraged to explore further areas of enhancement of FDA's internal Product Tracing System, which will be used during outbreak investigations.
- Receive an early release of the PFT-compiled summary report regarding this pilot, as well as PFT-branded merchandise.

Timeline

The timeline for this project is as follows:

TABLE 1: Timeline and Milestones

Milestone	Date
Pilot invitation released	June 15, 2026
Participant registration deadline	Ongoing
Draft submissions to PFT due	Ongoing
Sharing information with FDA	Ongoing

Pilot Output Framework

Outputs from this pilot include:

- Population of an electronic sortable spreadsheet (ESS).
- Narrative report (see Appendix B), including portions of the participant's traceability plan that explain the contents of the ESS, sent to PFT
- (Optional) An ESS, sent to the PFT Pilot Committee Working Group for review and feedback. Pilot participants may also send the data in machine-readable formats. Participants are strongly encouraged to include an accompanying data dictionary and any context the agency or PFT would need to understand the ESS, such as a description of how you assign your traceability lot codes. If this information is included in your traceability plan, please consider sharing the plan as part of the ESS submission.

Interested pilot participants are required to submit the following checklist (aligned with Appendix A) to indicate their intended outputs related to this pilot: Report Checklist for PFT Pilot 2 Participants – Fill out form

There is no direct requirement for how much data must be pulled to participate in this pilot program. Similarly, there is no requirement to conduct a pilot with all KDEs if some KDEs have yet to be implemented. Participants can de-identify or otherwise anonymize information in the ESS. Interested participants will receive information regarding ESS upload for PFT review and feedback.

Data Handling and Confidentiality

Participants are not expected to use real-time data; hypothetical or historic data may be used. Participants may also de-identify or otherwise anonymize information in their ESS submissions.

Participants who elect to send an ESS to the PFT Pilot Committee Working Group for feedback can choose to de-identify the spreadsheet before submission. Any feedback provided is educational in nature, does not reflect the views of PFT, and should not be considered regulatory guidance. ESSs shared with the Pilot Committee Working Group will be stored on a SharePoint site that restricts access to invited participants only; however, by sharing an ESS with the PFT Pilot Committee Working Group, participants acknowledge that the data is shared without an expectation of confidentiality.

Regarding narrative reports, participants may choose their preferred format for the final work product: either a company-submitted report or a PFT-created, de-identified general summary. Participants may also choose which audiences have access to view final reports or summaries. See Report Checklist for PFT Pilot 2 Participants for more information.

PFT can coordinate with participants to maintain public-facing confidentiality for submitted narrative reports. However, company names and identifying information must be disclosed to PFT in order to participate in the program.

How to Participate

Interested in this pilot or have questions about how to participate? Use the contact form located at https://pftraceability.org/pilot-program/ and reference “Pilot 2: Industry testing electronic sortable spreadsheets.”

Participation is voluntary and collaborative. This initiative offers the industry an opportunity to share practical implementation experiences that can inform FDA’s understanding of FTR readiness and potentially shape future guidance.

The Role of the Partnership for Food Traceability

The Partnership for Food Traceability (PFT) is coordinating this pilot program to enable more comprehensive and consistent collection of pilot learnings and to share those learnings with FDA. PFT is not designing or managing individual pilots. Instead, PFT provides a consistent framework for conducting pilots and reporting results, making it easier to compare learnings across participants. As a public-private partnership with FDA, PFT is well positioned to serve as a conduit for delivering collective pilot experiences to the agency. Learn more about PFT at https://pftraceability.org/.

References

FDA Food Traceability Rule

Product Tracing System | FDA

EPCIS Standard from GS1

Produce Traceability Initiative Traceability Data Recommendations

GS1 Traceability Data Recommendations

Partnership for Food Traceability

APPENDIX A: Instructions on completing your electronic sortable spreadsheet

The purpose of this pilot is for your company to test your ability to populate an electronic sortable spreadsheet (ESS) for one or more critical tracking events (CTEs) of your choosing, using your current system and data structures, within 24 hours. Please refer to https://www.fda.gov/media/181946/download?attachment for examples on how to complete an ESS for critical tracking events.

The ESS is one part of the report for this pilot. For other report items, refer to Appendix B.

Follow the steps below and enter your responses in this form to indicate what you will be providing as well as any legend information to decode the ESS.

Section 1: Fill out your name, company, and contact information, and describe which CTEs you will be targeting as part of this pilot.

- **Determine pilot scope.** Based on your industry, select the CTEs that apply to you for completion of this pilot exercise. A list of possible CTEs applicable by industry is shown below.

Industry	**Potential CTEs Applicable for This Pilot**						
	Harvest	Cooling	Initial Pack	First Land-Based Receiver	Shipping	Receiving	Transformation
Produce, shell eggs, or aquaculture farms that harvest, cool before packing, and pack	X	X	X		X		
Farms that do not cool or pack	X						
Packers of RACs		*	X		X	**	
Food repackers					X	X	X

Food manufacturers of FTL foods					X	**	X
Manufacturers transforming FTL foods into non-FTL foods						X	
Food distributors and warehouses					X	X	***
Retailers						X	
First land-based receivers				X	X		
Wild-caught seafood							

*If you are cooling before initial packing, this would be included.

**If you are receiving packed FTL RACs or other FTL foods, this would be included.

***If you are repacking an FTL food, then this would be assessed as “yes.”

- **Determine time scope for data collection and upload to the ESS**. PFT recommends including at least two weeks of activity in the ESS, if possible. If this is not possible, please annotate your chosen time frame.

- **Outline the categories of FTL Foods included in this pilot.** Choose all that apply from the list below. Please see the FTL website for more information
  - ❑ FTL Cheese
  - ❑ Shell Eggs
  - ❑ Nut Butters
  - ❑ Fresh Cucumbers, Fresh Herbs, Fresh Peppers, Fresh Melons, Fresh Tomatoes, Fresh Tropical Tree Fruits, Fresh Leafy Greens
  - ❑ Fresh Sprouts
  - ❑ Fresh Cut Vegetables or Fresh Cut Fruit
  - ❑ FTL Finfish
  - ❑ FTL Crustaceans
  - ❑ FTL Molluscan Shellfish
  - ❑ Ready-to-Eat Deli Salads
  - ❑ Non-FTL Foods

- **Determine locations in scope for this pilot.** PFT recommends that you complete this exercise with at least three locations (e.g., three shipping locations, or receiving from three farms). Please list below which locations you have selected to complete the pilot.
    - _____
    - _____
    - _____

Section 2: Your ESS.

- **In the Microsoft form,** please inform us how you define data within your ESS, what work product you will be creating, and whether you would like to share your ESS with the PFT Pilot Committee Working Group for feedback**.**

- **Fill out your ESS**. Time yourself for this exercise and provide feedback in your narrative report (see Appendix B) regarding how long it took to complete.

Section 3: Based on your ESS experience, write your narrative report (see Appendix B) and send to Ben.Miller@achesongroup.com and Angela.Ferelligruber@achesongroup.com.

APPENDIX B: Report Template

1. Description of Participant

a. **Organization Overview:** Describe your organization, supply chain role, and relationship to Food Traceability List products.

b. **Products and CTEs:** Describe the FTL products, categories, and CTEs included in pilot activities.

c. **Current Data Sharing Protocol:** Briefly describe your current systems, data structure, and capabilities for traceability data capture and submission to FDA. If your traceability plan addresses this, share the information outlined in 21 CFR 1.1315.

2. Summary of Pilot Approach

a. **Pilot Objectives:** What are you trying to learn or demonstrate?

b. **Scope and Timeline:** Describe the scope of pilot activities, the timeframe of data used, the time required to complete the pilot, locations included and any limitations.

c. **Scenarios Addressed:** Describe the real-world scenarios tested.

3. Pilot Activities

a. **Approaches Tested:** Describe the methodologies tested to complete an ESS or machine-readable spreadsheet (optional) for all CTEs included in your pilot scenario.

b. **System or Process Modifications:** Describe any system changes or process modifications required.

c. **KDE Documentation:** Describe KDE documentation methods and the accuracy of data mapping.

d. **Data Quality and Completeness:** Assess the quality and completeness of KDE information. Were there gaps or ambiguities?

4. Findings: Operational and Technical

a. **Operational Feasibility:** What worked well? What was challenging from an operational perspective? Was there any need to work with trading partners to obtain KDEs, and if so, how successful was that effort?

b. **Workflow Integration:** How did lot code capture and other KDE documentation integrate with existing workflows?

c. **System and Technology Considerations:** Describe system capabilities, limitations, and data format or exchange challenges.

5. Findings: Business and Organizational

a. **Cost and Resource Considerations:** What resources were required? What are the estimated costs for implementation at scale?

b. **Organizational and Change Management:** Describe training needs, process changes, organizational challenges, and stakeholder buy-in.

c. **Trading Partner Collaboration (if applicable):** Describe experiences working with upstream and downstream trading partners on KDE exchange.

6. Recommendations

a. **For Industry Stakeholders:** Based on your experience, what recommendations would you offer to other supply chain participants implementing KDE capture, documentation, and sharing?

b. **For FDA Consideration:** What guidance, clarification, or flexibility from FDA would support ESS submission?

c. **For Future Guidance Development:** What topics or scenarios would benefit from additional industry guidance or FDA clarification?

7. Additional Information (Optional)

a. Future implementation plans

b. Additional scenarios you plan to test

c. Technology or process innovations under development

d. Questions or topics for further industry discussion

e. Supporting data, diagrams, or workflow illustrations