

State/Territory Produce Safety Implementation Cooperative Agreement

Update on Farm Inventory, Regulatory Training process, On Farm Readiness Review and next steps

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AFDO Food Committee Meeting

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- Farm Inventory Update
 - Walkthrough current processes
 - Time lines
 - Future Plans
- Regulatory Training Plans and Process – FD226
 - Where regulatory training is now
 - Participants in development of course
 - Time Lines for future
- On Farm Readiness Review
 - NASDA is leading the process
 - Participants and Timelines
- Wrap up next steps, and
- Questions

- Background
 - Objectives of Farm Inventory Data Collection
 - Role of States
 - Role of FDA
- Short-Term: Data Collection
 - Data Collection Approach
 - Data Catalog
 - Data Template and Data Collection
 - Key Target Dates
- Long-Term: Inventory Management, Work Planning, and Inspections
 - FDA IT Vision
 - Current Status
- Data Security Concerns

Objectives of Farm Inventory Data Collection

- Collect data to help contact/locate farms to target implementation efforts
- Collect data to help characterize farms to inform risk prioritization (e.g., farm size, commodity)
- Collect data to support work planning and inspections

- Establish a process for identifying, verifying, updating, and sharing (with FDA) the farm inventory for the State
 - Process should be described in the State's multi-year plan
- Identify sources and/or mechanisms to collect farm inventory data
- Collect farm inventory data
- Verify the accuracy of data
- Utilize an electronic system to capture and share information with regulatory partners, including FDA
- Periodically update inventory data

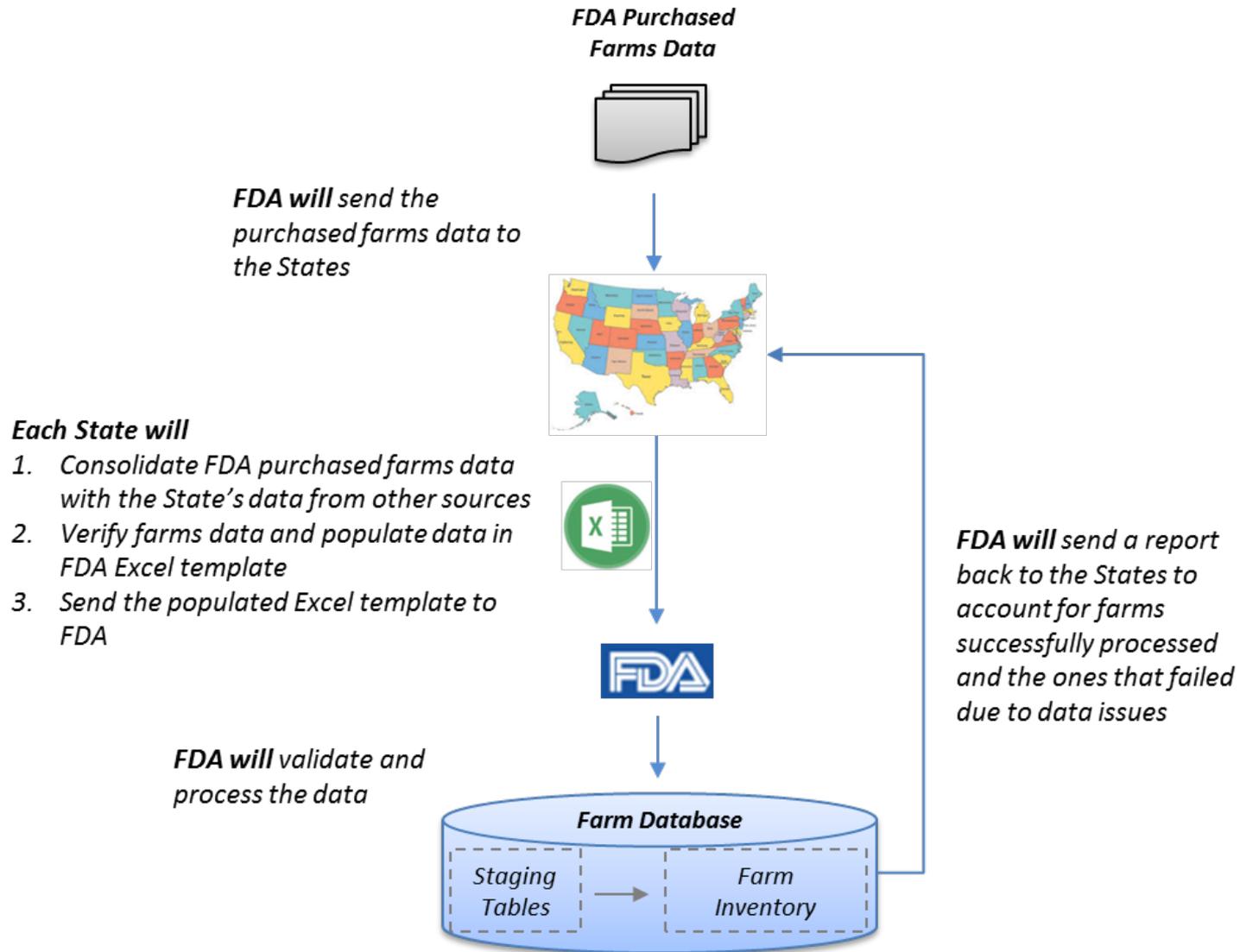
- Maintain a consolidated official produce farm inventory of both domestic and foreign farms
- Develop and maintain a centralized system to house produce farm inventory data
- Establish mechanisms for sharing data between States and FDA
- Identify and communicate data standards and elements
- General quality assurance and quality control (QA/QC) of produce farm inventory data
- Support State Produce Farm Inventory Development
 - Explore purchase of data from external sources
 - Establish produce farm inventory in States not participating in the State CAP

Short-Term: Farm Inventory Data Collection



- Short-term data collection focuses on States collecting verified farm data in:
 - Excel template provided by FDA
 - A purchased software such as WinWam, or
 - A new or modified system developed by the State
- To send farm inventory data back to FDA
 - All states should provide the data in the Excel template, including for states with an IT system (purchased or custom developed), if possible
 - Please notify your project officer ASAP if the data cannot be captured in the Excel template
- Each State will have an FDA web account to upload the Excel template when ready to send the farm inventory to FDA
 - An account will be created for each state
- FDA will validate and process the data
 - States will be provided a report (in Excel format) of farms successfully processed as well as farms with issues such as incomplete or incorrect values
 - Corrected or new data can be resubmitted through the same process until a long-term solution is available
 - FDA will store data received in a consolidated official produce farm inventory

Data Flow for Short-Term Data Collection



- Data Catalog contains farm inventory data elements & descriptions
- Data Catalog was finalized April 2017 with input from NASDA & State Reps
- Data elements can be grouped into the following categories:
 - IDs (State Unique ID, FEI and DUNS Number)
 - Farm Name, Address, and GIS Info
 - Commodity and Activity Info
 - Sales Info
 - Seasonality

- The Farm Inventory Data Catalog is categorized into:
 - **Required Data Elements:** Key fields that help to identify the farm and relevance to the Produce Safety Program. States should make attempts to collect data for a required field but can specify “not available” if the info cannot be identified. Include:
 - Farm State ID
 - Farm Name
 - Physical Address
 - Phone
 - Farm Size based on Average Produce Sales
 - Covered Produce (Y/N)
 - Growing Period
 - **Recommended Data Elements:** Recommended fields will help with work planning and inspections. Recommended data elements can be collected over time (repeat interactions with the farmer) or may be collected during an inspection. These data elements can be left blank if not available or known.
 - **Optional Data Elements:** Optional data elements are optional, and can be left blank.

Verification of Farm Inventory Data

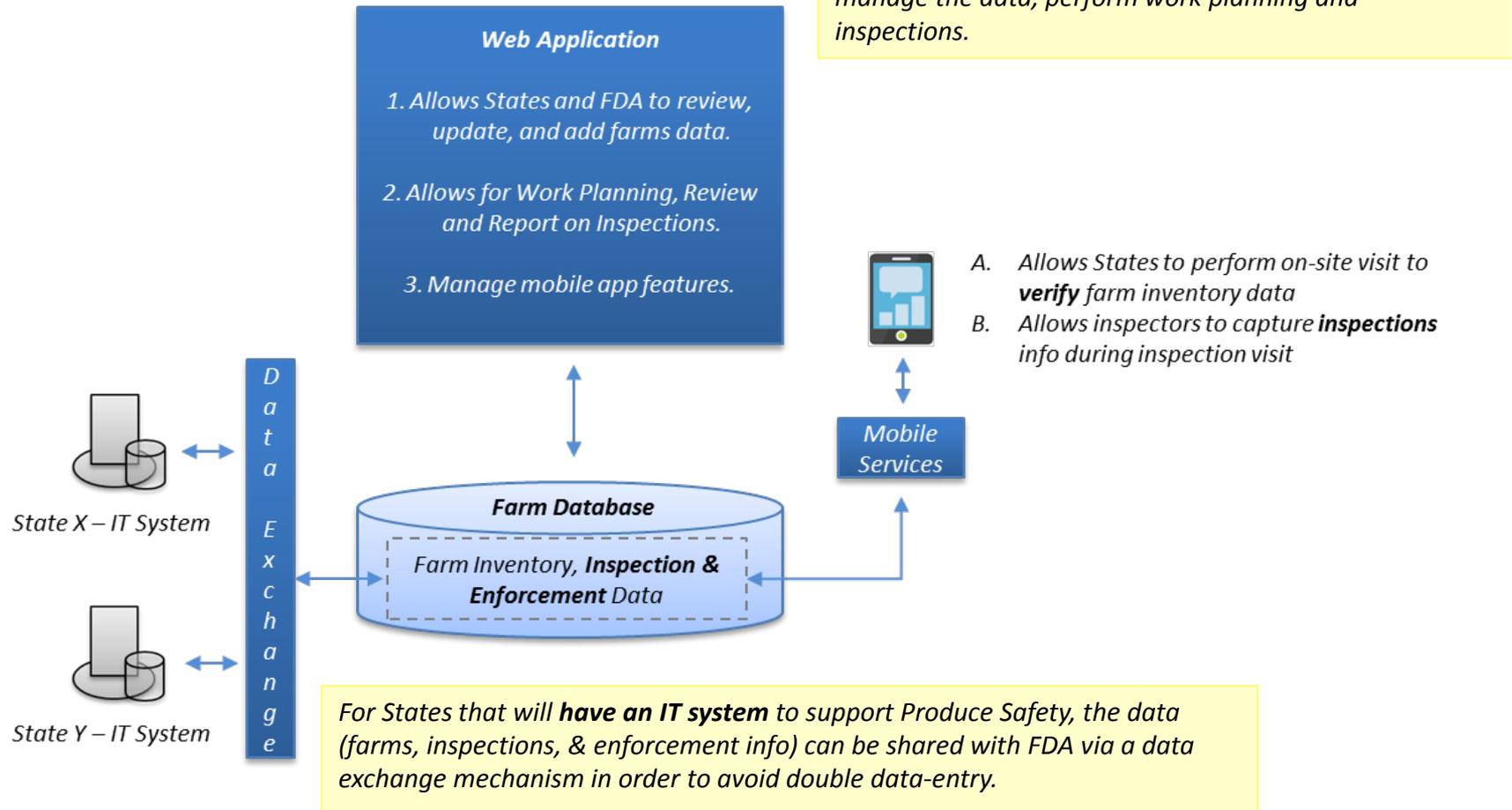
- For external data sources (such as purchased data or farm registries), we recommend that States verify the required data elements through the verification process prior to sharing that data with FDA.
 - Verification can occur through informational visits, phone calls, inspections or other direct interactions with the farmer.
 - At a minimum, we ask that States verify: Name, Address, whether the farm is still in business, whether the farm grows/harvests/packs/holds covered produce, and whether the farm averages more than \$25k in produce sales.
- Verification of voluntary registration web sites
 - States should, at a minimum, review farm inventory data received through a voluntary registration portal to ensure the data appears accurate, complete and fields were filled out correctly.
 - If data appears inaccurate or incomplete, States may want to consider a more robust verification process (e.g., contact the farm directly) prior to sharing that information with FDA.
- Data collected directly from the farm through other mechanisms (e.g., collected through direct mailing, phone, or other direct interaction with farmer) would not need additional verification

- FDA developed an Excel template in conjunction with State Representatives and NASDA
- States should start collecting farm inventory data using available data and resources at this time
- FDA is in the process of purchasing farms data from an external data source and will share the data with States by summer 2017
 - Once FDA announces the vendor, States will have the option to purchase data from other sources to support farm inventory efforts.
- Each State will need to
 - Consolidate FDA purchased farms data with other sources identified by the State
 - Verify farms data via phone, farm visit, or other methods and populate data in the FDA Excel template
 - Send the populated Excel template to FDA

- **May 2017:**
 - Each State has the option to populate the template with 5-10 farm records in the FDA Excel template and send back to FDA for review with any questions
- **May – Sep 2017:**
 - Each state will continue to collect and verify farm inventory and populate the data in the Excel template
- **Summer 2017**
 - FDA will send purchased data to States
- **Sep – Nov 2017:**
 - Each state will send verified farm inventory to FDA
- **Oct – Dec 2017:**
 - FDA will review, validate, and process inventory from the States
 - FDA will send a farm inventory report back to the States
 - FDA will coordinate with each state to resolve any questions or issues

- FDA will develop an IT solution to support both States with an IT system and States without an IT system
- For States that **will not** have an IT system to support Produce Safety Program, FDA will provide an IT solution to
 - **Manage Farm Inventory:** Provide the ability to search, view, update, and add farms
 - **Perform Work Planning:** Provide data and tools for work planning
 - **Perform Inspections:** Provide mobile solution to perform on site inspections
- For States that **will** have an IT system to support Produce Safety Program, FDA will work with each of the States to
 - Identify the technology stack (Java, .NET, WinWam, etc.) to determine if the State's IT solution can integrate with FDA's data exchange mechanism
 - If needed, alternative data exchange mechanism can be explored

Long-Term: FDA IT Vision



- FDA is working with State Representatives and NASDA to gather **requirements** for
 - **Farm Inventory Management:** Need to determine the users and roles for each state to manage data
 - **Work Planning:** Need to identify the common and differences in the approach for each state to perform work planning
 - **Inspections:** Need to determine what should be covered during an inspection
- For the **design** of the IT solution
 - FDA is considering existing FDA capabilities that can support the Produce Safety Program
 - FDA needs to determine if current data exchange mechanism is sufficient to integrate with the different State systems
- Timeline has not been identified for the long-term solution
 - Target date for Farm Inventory Management solution will be determined by the end of May / early June
 - Target date for Work Planning and Inspections solution will be determined once the requirements are better defined

- Under FOIA, certain records may be withheld in whole or in part from the requestor if they fall within one of the nine FOIA exemptions
 - Certain farm data would likely fall into the exemption that protects trade secrets and confidential commercial or financial information
 - Types of information FDA would likely protect from disclosure include sales volume and acreage
- FDA is working with our agency FOIA experts and OCC to get some definitive feedback on what data elements from the Data Catalog can be protected

- FDA is working with state partners to develop course
 - State participants are Matt Fout OH, Anita MacMullan NC, Christian Kleinguenther NJ, Roger Beekman WA and Valerie Gamble MN.
 - FDA staff represent, CFSAN, ORA PSN and the National Experts on the workgroup.
 - FDA has contracted with course design specialist to facilitate the course development process.
- The first walk through of the course will be July 12-14, 2017
 - Participants will see the course in a 90% complete form at this time and make final comments and recommendations to consultants.

- Final course schedule for delivery is in the process of being developed, should be published Fall of 2017.
 - Current plan is for three and a half days of class time with half day on the farm

- Pilot delivery will be in August 15-18, 2017 in Salem Oregon.

- Based on the training needs survey FDA is planning on four courses next year.
 - Please complete training survey when it comes out again as that is what we use to determine the number and locations of the course offerings for the coming year.

- What is it?
 - A voluntary non-regulatory, pre-inspectional “readiness” review for covered farms
 - Familiarize farmers with FSMA Produce Rule, FDA and State regulators
 - Promote coordination between farmers, regulators and educators
- What is it composed of?
 - A resource manual (that links to the questionnaire conversations) that compliments the PSA training and other available resources.
 - A decision tree to identify what areas will be covered by the questionnaire (self assessment).
 - A walking around questionnaire to facilitate conversations between farmers, regulatory and educational staff involved.
 - Divided into components: Worker Health and Hygiene, Pre-planting and growing season, Pre-Harvest and Harvest, Post-Harvest, holding and storage assessments.



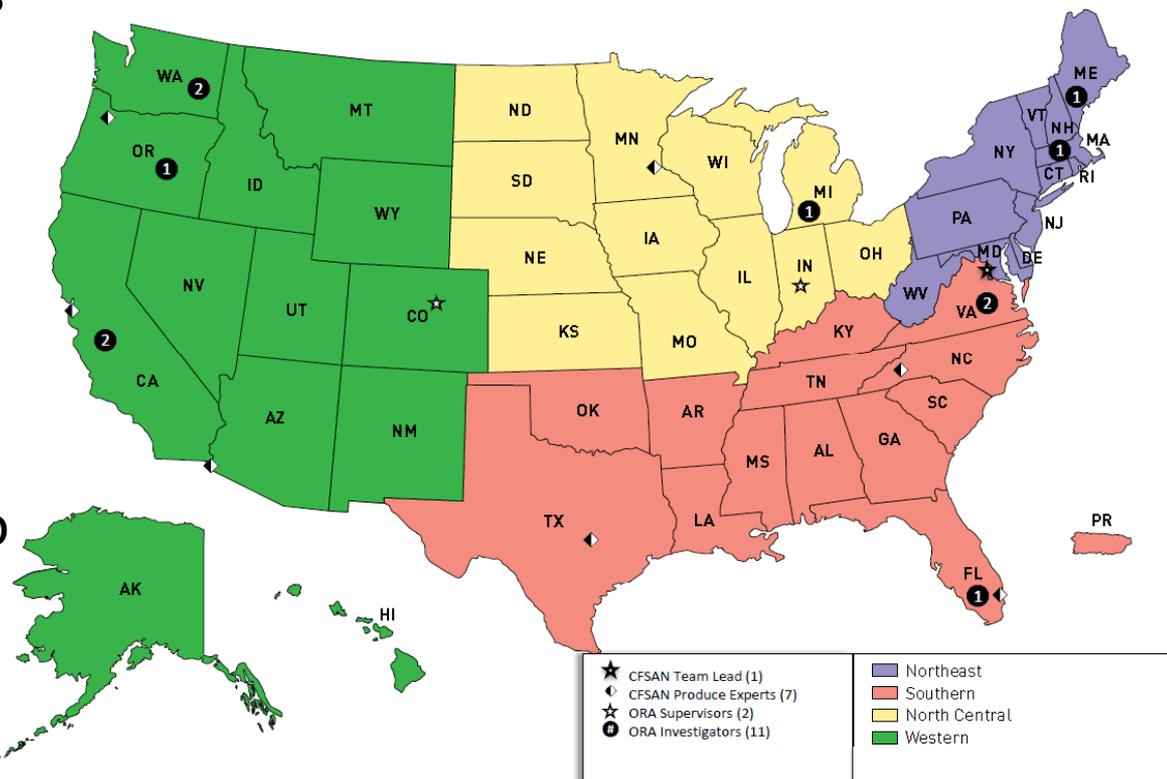
On Farm Readiness Review

- NASDA has been working with a group of state regulatory staff, FDA regulatory staff, FDA CFSAN staff and Cooperative Extension Educators to develop the On Farm Readiness Review Tool and resources.
 - Tool has been piloted through numerous iterations and is approaching it's final form
 - The tool has been used in a variety of states on a variety of farms from north to south and east to west.
 - Workgroup Participants include regulatory representatives from NC, MI, OR, VT, FDA (both ORA and CFSAN), USDA, and educators from the PSA, New Jersey, Florida, Michigan and North Carolina along with staff from NASDA.

- NASDA will be your point of contact for the documents and training opportunities associated with the On Farm Readiness Review, please watch their website and your emails from NASDA for the latest and most up to date information.
- Currently we anticipate the final document will be ready in the early fall of 2017.
- The educators are working on a schedule of training for the US which should be published also in the early fall of 2017.

- Questions?
- Don't forget the FDA's website and the Produce Safety Network which houses resources for your use and for the most up to date info, maps and contact info go to: [Food Safety Modernization Act \(FSMA\) > Building the Produce Safety Network](#)

Produce Safety Network (PSN)



January 2017