Welcome, Overview, and Goals of Produce Safety Consortium Meeting

- Bob Ehart, Senior Policy and Science Advisor, NASDA
- Melinda Plaisier, MSW, Associate Commissioner for Regulatory Affairs, FDA
- Erik Mettler, M.P.A, M.P.H, Associate Commissioner for Foods and Veterinary Medicine, FDA
Commissioners, Secretaries and Directors

- NASDA President, Commissioner Steven Reviczky, Connecticut Department of Agriculture
- Natalie Krout-Greenberg on behalf of Secretary Karen Ross, California Department of Food and Agriculture
- Commissioner Don Brown, Colorado Department of Agriculture
- Commissioner Steve Troxler, North Carolina Department of Agriculture
- Director Jaime Clover Adams, Michigan Department of Agriculture and Rural Development
Remarks from CFSAN

- Jim Gorney, Senior Advisor for Produce Safety, Center for Food Safety and Applied Nutrition, FDA
Got Questions?

Remember to submit your questions to the Q&A team!

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On Farm Readiness Review (OFRR), Progress Update; Manual Development

- Bob Ehart, NASDA
- Gary Weber, NASDA
- Michelle Danyluk, University of Florida Extension
On Farm Readiness Review
Perspectives: Panel Discussion

• Michelle Danyluk, University of Florida Extension, Moderator
• Steve Patton, California
• Sydney Armstrong, Florida
• Jessica Lepper, University of Florida
• Jacob Reynolds, FDA
On-Farm Readiness Review
Perspectives:
Panel Discussion

Michelle Danyluk
University of Florida
03/06/18
mddanyluk@ufl.edu
OFRR Training

• Interactive training spread over multiple days
  • classroom training
  • instructor lead OFRR on a farm
  • role play
  • student lead OFRR on a farm
## OFRR Classroom Agenda

<table>
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<th>Session</th>
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<td>Welcome and Introduction &amp; Pilot Overview</td>
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<tr>
<td>Introduction to On-Farm Readiness Reviews</td>
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<tr>
<td>Expectation of Assessors</td>
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<tr>
<td>On-Farm Etiquette</td>
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<tr>
<td>Walk Around Questions and Walkthrough</td>
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<tr>
<td>Farm Visit Logistics</td>
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</table>
OFRR Tool

• 15 tabs of information
1. Contents and Welcome
2. Decision and Exemption Tools
3-14 Readiness Review Modules
15. Resources
OFRR Resource Document Modules

- Worker Health & Hygiene
- Wild and domestic animal
- Soil amendments
- Preharvest water
- Preharvest sanitation
- Preharvest worker training

- Harvest water
- Harvest sanitation
- Harvest worker training

- Postharvest water
- Postharvest sanitation
- Postharvest worker training
OFRR Process

1. Pre-review work

2. On The Farm
   - Initial Interview
   - Walk Around
   - Final Meeting

3. Evaluation
OFRR Perspectives – Panel Discussion

Sydney Armstrong
• FDACS
• FSMA Coordinator, Division of Fruit and Vegetables
• Sydney.Stone@freshfromflorida.com

Jessica Lepper
• University of Florida
• Training Specialist
• jal20xox@ufl.edu

Jacob Reynolds
• FDA
• PSN ORA
• jacob.reynolds@fda.hhs.gov

Steve Patton
• CDFA
• Chief, Inspection and Compliance Branch
• steve.patton@cdfa.ca.gov
Summary

- The OFRR process requires commitment
  - Requires knowledge and comfort with the PSR
  - Requires overcoming our inherent cultural understanding of GAPs, Best Practices, and Audits
- Provides assessors the opportunity to learn more about agriculture
- Opportunity to use the OFRR tool in alternate ways (i.e. commodity specific group training) exist
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Model Produce Safety Implementation Framework; Subgroup Accomplishments and New Subgroup Plans

- Bob Ehart, Senior Policy and Science Advisor, NASDA
Model Framework

• History
• First version
• Second version
• Third version
Chapters

- Alignment & Consistency
- Foundation of Law
- Financial Support
- Outreach & Education / Compliance & Enforcement
- Work Planning
More Chapters

- Information Sharing
- Regulator Training
- Accessing Laboratory Resources
- Technical Assistance
- Dispute Resolution
- Infrastructure
Current Activities

• On-Farm Readiness Review
• Regulatory Training
• National Consortium Meeting Planning
• State Strategic Plan Development
• Inspection Approach
  • Defining Enforcement Actions
  • Developing an Inspectional Protocol
  • Defining FDA / State Roles
Upcoming Activities

- Charge Documents
  - Recall Process
  - Disaster Response & Produce
  - Collecting & Sharing Education & Training Issues
  - Farm Inventory – Aggregate Data Sharing
  - Final Inspectional Report
Future

• New additions
• Keeping it alive
• Training program
• One copy per state
How to stay up to date

• The Framework is the roadmap for creating a state program
• It will be a living document – with continuous improvements, edits and modifications
• Questions?
• Contact bob@nasda.org, jim@nasda.org, carolp@nasda.org, janell@nasda.org
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2018 Annual Meeting
National Consortium for Produce Safety Program Development
March 6 – 8
Irvine, California

NASDA
Inspectional Approach – Introduction

- Joe Reardon, North Carolina
- Jennifer Thomas, FDA
Standardized Inspection Protocol

- Natalie Adan, Georgia
- Kevin Gerrity, FDA
Standardized Approach to Produce Farm Inspections
Standardized Approach to Produce Farm Inspections

- NASDA / FDA recommended approach for routine produce farm inspections, with an introduction to for-cause and unannounced inspections
Standardized Approach to Produce Farm Inspections

• Role and Expectations of PSR Farm Inspector

• Determine compliance with PSR
• Provide educational resources
• Provide guidance documents
• Build professional relationships
Standardized Approach to Produce Farm Inspections

• Step 1: Prepare for inspection
  • Farm etiquette
    • Scheduling flexibility
    • Farm check-in / initial meeting location
    • Farm rules
    • Driving on farms
    • Gates, private residences, farm road access
Standardized Approach to Produce Farm Inspections

• Step 1: Prepare for inspection
  • Biosecurity
    • Adhere to farm biosecurity practices
    • Boot maintenance
    • Personal health & hygiene
    • Vehicles
    • Inspection flow
Standardized Approach to Produce Farm Inspections

• Step 1: Prepare for inspection
  • Safety
    • Heatstroke
    • Communications
    • Farm equipment
    • Farm water systems
    • Wildlife
    • Confined spaces
Standardized Approach to Produce Farm Inspections

• Step 2: Scheduling the inspection
  • Determine if PSR applies to farm (FDA decision tree)
  • Try to schedule during covered activities
  • Schedule flexibility
  • High level overview of inspection process
  • Send informational packet
Standardized Approach to Produce Farm Inspections

• Step 3: Initiate the inspection
  • Punctual
  • Prepared
  • Present ID / Inspection Notice
  • Coordinate to observe covered activities
Standardized Approach to Produce Farm Inspections

• Step 4: Conducting the inspection
  • Biosecurity & Inspection Flow Considerations
  • Inspection Form
    • Consistency
    • Comprehensive PSR Coverage
Standardized Approach to Produce Farm Inspections

• Step 4.1: On-farm regulatory observations
  
  • SP3 reference tool, excel file tabbed for inspection relevant sub-sections of the PSR
  • Questions to ask with abbreviated regulatory citations
Standardized Approach to Produce Farm Inspections

• Step 4.1: On-farm regulatory observations
  • C- Personnel Qualifications and Training
  • D-Health and Hygiene
  • E- Agricultural Water
  • F- Biological Soil Amendments of Animal Origin
Standardized Approach to Produce Farm Inspections

• Step 4.1: On-farm regulatory observations

  • I- Domesticated and Wild Animals
  • K- Growing, Harvesting, Packing, & Holding Activities
  • L- Equipment, Tools, Buildings, & Sanitation
  • P- Variances
Standardized Approach to Produce Farm Inspections

- Step 4.2: Regulatory record review
  - Training
  - Biological Soil Amendments of Animal Origin
  - Food Contact Surface Cleaning and Sanitizing
  - Exemptions
  - Alternatives & Variances
Standardized Approach to Produce Farm Inspections

• Step 4: Discussing Regulatory Concerns
  • Discuss each concern at the time of each observation
  • Provide regulatory references and scientific rationale
  • Document corrective actions and commitments
  • Utilize systems thinking approach
Standardized Approach to Produce Farm Inspections

• Step 5: Formally Close the Inspection
  • Summary of discussions held during the inspection
  • Solicit additional questions from Farmer
  • Provide inspection summary report to the Farmer
  • Discuss next steps
Standardized Approach to Produce Farm Inspections

• Step 6: Submit Farm Inspection Report
  • Adhere to your Agency’s procedures and practices
Standardized Approach to Produce Farm Inspections

• Step 7: Scheduling Follow-up or Unannounced Inspections
  
  • Unresponsive Farmers
  • Inadequate corrective actions to past food safety issues
  • Complaints, recalls, outbreaks
  • Hostile situations
Standardized Approach to Produce Farm Inspections

• Appendices

• What to Expect of a Regulatory Inspection Handout
• Produce Farm Safety Considerations
• PSA Records Required by the PSR
• Pre-Inspection Call Job Aide
• Qualified Exemption Job Aide
• Commercial Processing Exemption Job Aide
• FDA Decision Tree
Standardized Approach to Produce Farm Inspections Summary

- Intended to drive National consistency
- Currently under review (DRAFT)
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Compliance and Enforcement Template

- Katherine Simon, Minnesota
- Jennifer Thomas, FDA
Compliance & Enforcement (C&E) Template

Katherine Simon
Assistant Division Director
Food & Feed Safety Division
Minnesota Department of Agriculture
Work Group Charges

• Develop processes and mechanisms for initiation and application of enforcement actions, including follow-up, in response to inspectional observations, to ensure consistent application of the regulation across jurisdictions.

• Provide a consistent coordinated approach to enforcement actions, when needed.

• Could be different when inspections are done under state law vs. under commissioning.
Work Group Charges

• Communications, information sharing piece.
• Develop joint enforcement strategies. Consider automatic sharing of information for all enforcement actions, and establish triggers for when joint enforcement may be necessary.
• Develop a plan for follow-up timing after an enforcement action or violative inspection.
WG Proposal

• Template for C&E strategies
• Provide consistency and uniformity for C&E
• Decision Tree
• Descriptive Narrative

Compliance and Enforcement (C and E) Action Template for the Produce Safety Programs

I. Purpose of the C and E template:
   a. The purpose of this document is to provide a template for compliance and enforcement strategies. Use of this template will provide consistency and uniformity when addressing compliance and enforcement issues.

II. Definitions
   a. Egregious Condition: A practice, condition, or situation on a farm or in a packing house that is reasonably likely to lead to:
      • Serious adverse health consequences or death from the consumption of or exposure to covered produce;
      • An imminent public health hazard is posed if corrective action is not taken immediately (example: edible portions of produce contacting a potential source of contamination).

   b. Follow-up Inspection: a subsequent inspection that occurs to allow review of an issue or concern that was noted on a previous inspection.

   c. For-Cause Inspection: an inspection that occurs in response to a specific issue or concern, such as an outbreak, reported complaint, or recall. A “for-cause” inspection could include a follow-up inspection.

   d. Initial Inspection: an inspection that is the first regulatory inspection activity that a farmer has experienced to evaluate compliance with applicable regulations. The initial inspection should be educational focused unless egregious conditions are observed.

   e. Routine/Surveillance Inspection: Regularly scheduled (pre-announced) inspection to evaluate a farm’s compliance with applicable regulations.

III. General Principles
   a. The overall implementation approach for the Food Safety Modernization Act (FSMA) regulations is “educate before and while you regulate.” This C and E template embraces this concept by utilizing a progressive and flexible approach to compliance and enforcement. This is done by acknowledging that enhanced compliance and enforcement strategies may

   *疑似被遮挡的句子*
What it is NOT

• Standard operating procedure
• Prescribed actions
• Legal authority
Narrative Elements

• Definitions
• General Principles for Template Use
• Progressive Enforcement Concept
• Decision Tree Use
• Communications
General Principles

Terminology varies - examples:

- Letter of information
- Letter or notice of corrective action
- Warning letter
- Corrective Action Plan
- Educational session
- Negotiated agreements
- Notice of potential compliance or enforcement actions
- Monetary Penalties: Administrative, Civil, Criminal
- Court compelled actions
- Stop Sale
- Seizure/embargo/administrative detention
- Court Injunction
General Principles

• Educate before and while you regulate
• Consistent approach to determine regulatory action
• Risk-based – focus on public health impact
• Immediate corrective actions and long term corrections
• Assumption - farmer is notified with the expectation to take action
Progressive Enforcement

- Clear progression
- Scaled to match observations
- Key factors to assess though Decision Tree
- Purpose of C &E action must be clear
Progressive Enforcement

- **Voluntary compliance** - farmer elects to make changes after notification
- **Structured compliance** - ensure that the farmer follows through on non-compliance issues to prevent public hazards
- **Elevated compliance** - prevent or limit a farmer’s operation to protect public health due to uncorrected significant public health issue
- **Scope** - nature of the violation impact on the produce
Decision Tree Elements

- Inspection Type
- Evaluation of Severity of Observed Conditions
- Inspection History
- Regulatory Action to Consider
1. Inspection
2. Routine/Surveillance, Follow-up, For-Cause or Investigation
Observed Conditions

• Egregious Conditions
• Conditions that **MAY** cause contamination
• Conditions that **WON’T** cause contamination
• All other conditions
Inspection History

• Previous notification of observation/issue

- All other conditions
  - Conditions may cause produce contamination
  - Conditions won't cause produce contamination

 Has Farmer been previously notified of the observation or issue?
  - Yes
  - No
  - Yes
  - No
Regulatory Actions Considered

Immediate actions must be initiated to ensure adequate mitigation and correction of conditions.

Is produce still under the control of the farm?

Yes – Evaluate for embargo and disposition. No recall necessary if product is contained at farm.

No – Produce is in commerce – recall, embargo, stop sale if product has left farm.

Yes:
1. Discuss observed conditions with farmer;
2. Establish timeline for corrective actions and preventive measures;
3. Document findings on inspection report;
4. Schedule a re-inspection within 10, 30, 60 or 90 days; and,
5. Determine if regulatory letter or other enforcement action is warranted;
6. Communicate findings to FDA

No:
1. Discuss observed conditions with farmer;
2. Determine whether any produce has left the farm;
3. Establish timeline for corrective actions and preventive measures;
4. Document findings on inspection report;
5. Determine if information, regulatory letter, re-inspection or follow up during next routine inspection is warranted.

Provide outreach and education, resources for:
1. Training;
2. Guidance Documents;
3. Technical Assistance Network;
4. On-farm direct technical assistance.

Yes:
1. Discuss observed conditions with farmer;
2. Agree on timeline for corrective actions and preventive measures;
3. Document findings on inspection report;
4. Review conditions during next routine inspection;
5. No further action indicated.

No:
1. Discuss observed conditions with farmer;
3. Review conditions during next routine inspection;
4. No further action indicated.

March 5, 2018
Communication points

• Designed to harmonize the regulatory response
Summary

• Structured approach
• Flexibility for specific situational details
• Identifies progression
• Clear communication points
Questions?

Katherine Simon
Minnesota Department of Agriculture

Katherine.Simon@state.mn.us
651-201-6596
Got Questions?

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Summary of Inspectional Approach
Discussion

• Joe Reardon, North Carolina
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Produce Safety Regulator Training – Development and Execution

- Patricia Alcock, FDA
- Tim Slawinski, Michigan
NASDA/FDA Training Collaboration

Agenda

• Communication Working Group
• Prioritization Chart
• NASDA Training Needs Survey
• FDA FY19 Training Needs Survey
NASDA Survey

- Number of Inspectors in Years 2 & 3

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- Total 212
  - Out of 36 responses
NASDA Survey

• Inspector Experience
  • 85% - Background in Food Safety
  • 76% - Experienced with Produce Farmers
  • 65% - Experience with Food Inspections
  • 50% - 3rd Party Audit Experience
  • 47% - Experience with Produce Production
NASDA Survey

• Training Priorities
  • 83% - Food Inspection Technique
  • 83% - Regulatory Foundations
  • 80% - Preparing Documentation
FDA FY19 Training Needs Survey

• Sent to Food Safety Regulatory Partners
• FD226 is Included
  • Produce Inspections for Regulators
• Due 3/16/18 to OTED@fda.hhs.gov
Questions?

Tim Slawinski
MDARD
(517) 420-5364
slawinskit@michigan.gov
AGENDA

- Brief History
- Course Description & Goals
- Course Outline
- Course Pre-requisites
- FY18 Course Schedule
- Considerations for Regional Meeting Discussions

NOTE: Information is available on FOODSHIELD: Produce CAP Conference Call dated 10/25/17
BRIEF HISTORY OF PRODUCE TRAINING

• FSMA Rules Established
• Job Analysis Collaboration
• Course Development Collaboration
• Training Plan Development and Collaboration
• 2017 National Consortium Discussion
• FD226 Produce Inspections for Regulators Pilot Program
• FDA Produce Cooperative Agreement Teleconference: 10/25/17
FD226 COURSE DESCRIPTION

This is a 3.5 day training course for participants to learn and apply a systematic approach to inspect produce farms based upon the Produce Safety Rule and to document violations of this regulation observed during the inspection.
FD226 COURSE DESCRIPTION

• This course will prepare students to apply regulatory requirements to the design, planning and performance of produce farm inspections.
• Participants will apply knowledge for conducting on-farm inspections of produce farms.
• All elements of conducting an inspection, including planning, sampling, providing education, and issuance of regulatory corrective action will be discussed.
Objectives: Upon completion, participants will be able to:

1. Define key parameters of a produce farm inspection.
2. Identify the farms that are covered by the Produce Safety Rule and will be able to determine the jurisdictional responsibilities of collaborating regulatory agencies during a produce farm inspection.
3. Identify components for planning a produce farm inspection.
4. Conduct a produce farm inspection.
5. Describe activities of a produce farm that will be relevant to the conduct of a produce farm inspection and be able to record key observations.
6. Conclude the inspection and document.
FD226 COURSE OUTLINE

DAY 1
• Introduction and Course Overview
• Unit 1: Foundations of Produce Farm Inspections
• Unit 2: Jurisdictional Considerations for Produce Farm Inspections
• Unit 3: Planning the Inspection

DAY 2 - 4
• Unit 4: Conducting the Inspection:
• Unit 5: Produce Farm Visit
• Unit 6: Concluding the Inspection and Regulatory Follow-Up
• Final Exam
Produce Inspections Farm Tour

- Produce Farm tour includes:
  - growing, soil amendments in use, harvesting, packing, agricultural water sources, packing house, clean break, adjacent land use, tools and equipment, animal/pest control, observation of employee practices/training, pesticide storage and handling, and storage of RACs.
Communication and Soft Skills

• Soft skills are reinforced throughout the courses and will be strengthened through role play activities by the instructors in modules and interactions.

• Students will be taught to effectively communicate, respond and provide educational resource materials with the growers/farmers.
1. ORA’s New Hire Investigator Training Program or equivalent – Inspectional Foundation Training
2. Level 1 Investigator Certification (ORA Staff Only)
3. Produce Safety Alliance Grower’s Course or Produce Safety Alliance Train the Trainer Course
4. Introduction to Horticultural Production for Human Consumption Web Course (FD8011W)
5. Produce Safety Rule Web Course (FD8012W)
# FY ‘18 FD226 CLASS SCHEDULE

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<td>Katherine Tracy</td>
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FD226 Improvements

1. Strengthened the instructor and student manuals and course materials.
2. Strengthened references to the Produce Safety Rule regulation (PSR) and preamble.
3. Clarified terminology to be consistent with the PSR.
4. Will provide more general information on pathogens related to produce; sanitizers/cleaners and wells.
5. Strengthen continued communication with the grower/farmer on any findings throughout the inspection and tie to public health.

-Educate before/while we regulate
6. Strengthen the egregious findings section of training.
7. Strengthen the required records under PSR vs. best practices.
8. Inspection approach will be modified when NASDA/FDA documents are cleared through the Agency.
9. Compliance/Enforcement section will be modified when NASDA/FDA documents are cleared through the Agency.
10. Update online modules based on feedback.
Regional Discussion:
Points of Collaboration & Communication

• Experience level of your produce inspector(s)?
• Planned Training Plan for your produce inspector(s)?
  – How does it change based on the staff hired?
  – Where can you leverage FDA and State training resources?
• NASDA and FDA will continue to finalize the foundational knowledge training available via online.
  – Performance of inspections?
  – Familiarity with farms?
Regional Discussion: Points of Collaboration & Communication

• Key areas to leverage with other States?
  – Food Safety Background?
  – Public Health Principles?
  – Inspection Foundation Processes?
    • Law, Regulations and Authorities
    • Communication Skills
    • Safety
  – Farm Experience/Site visits?
  – Mentoring/Coaching?
Next Steps?

- Continued collaboration with NASDA
- Update FD226 with inspection approach and compliance/enforcement plans when vetted through Agency.
- Continue training FDA/State staff with FD226.
- Determine appropriate time and training modality to update past FD226 course attendees.
- Feedback loop and evaluation for FD226 as continuous course improvements
QUESTIONS?
CONTACT INFORMATION

PATRICIA L. ALCOCK
DIRECTOR
FDA/GROP/ORA/OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT
TEL: 301-796-4299
EMAIL: PATRICIA.ALCOCK@FDA.HHS.GOV
EMAIL: OTED @FDA.HHS.GOV
Got Questions?

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Farm Inventory

- Jeff Farrar, FDA
- Jennifer Thomas, FDA
Day 1 Wrap Up and Daily Q&A

- Bob Ehart, NASDA
- Jeff Farrar, FDA
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Day 3 Opening Remarks

• Dr. Barb Glenn, Chief Executive Officer, NASDA
Our Strong Partnership on Food Safety

Barb Glenn, CEO, NASDA

National Consortium for Produce Safety Meeting
March 6 – 8, 2018
About NASDA: Our Mission

- Our mission is to grow and enhance agriculture by forging partnerships and creating consensus to achieve sound policy outcomes between state departments of agriculture, the federal government, and stakeholders.
NASDA - FDA Cooperative Agreement
FSMA Produce Safety Team

Chief Executive Officer
Dr. Barbara P. Glenn

Executive Director, Public Policy
Nathan Bowen

Senior Science & Policy Advisor
Bob Ehart

Associate Director, Public Policy
Food Safety & Programs
Janell Hendren

CA Produce Safety Project Manager
Jim Melvin

Subject Matter Expert
Joe Reardon

Subject Matter Expert
Gary Weber

CA Assistant Produce Safety Project Manager
Carol Perrier
NASDA - FDA Cooperative Agreement
FSMA Animal Food Team

Chief Executive Officer
Dr. Barbara P. Glenn

Executive Director, Public Policy
Nathan Bowen

Associate Director, Public Policy Food Safety & Programs
Janell Hendren

Senior Science & Policy Advisor
Bob Ehart

Administrative Coordinator
Felicity Mejeris
Vision

Enhanced public health and food safety for consumers, through successful implementation of FSMA in a partnership of farmers, state departments of Agriculture, and US FDA, and others.
Goal

Continue to enhance NASDA Team work on FSMA implementation by executing goals and objectives of the NASDA- FDA Cooperative Agreement.
Objectives

1. Continual progress in both NASDA- FDA Cooperative Agreements while assuring expectations are commensurate with adequate resources.

2. The NASDA Team works together toward the expectations of the NASDA-FDA Cooperative Agreements.

3. Advancing NASDA Cooperative Agreement progress, while assuring strong NASDA policy work.
Additional NASDA Activities

• NASDA participates with FDA on monthly calls with the states

• NASDA has a monthly call for/with states

• NASDA organizes the quarterly Implementation Group meetings between NASDA and FDA

• NASDA establishes and coordinates the SubGroup activities to assist FDA and the States
NASDA 2018 Policy Priorities

- Cooperative Federalism
- FSMA Implementation
- International Trade and harmonization
- Farm Bill Priorities
Our Strong Partnership on Food Safety

Barb Glenn, CEO, NASDA
barb@nasda.org
202-296-9680
Day 3 Opening Remarks

• Commissioner Richard Ball, New York Department of Agriculture
Recap of Day 2 and Q&A

- Joe Reardon, North Carolina
- Barbara Cassens, FDA
Water Rule Update and Report on Water Summit with Panel Participants

• Betsy Bihn, Produce Safety Alliance, Moderator
• Samir Assar, FDA
• Martha Roberts, Florida
• Bob Ehart, NASDA
Report on Water Summit
Water Summit Stats

• **108 people in Covington, KY; participants and facilitators**
• **Online attendees from US, PR, and 7 foreign countries**
  • 202 attended on Day 1. 143 came back for some or all of Day 2. 59 (29%) did not come back for Day 2
  • 188 attended on Day 2. 45 (24%) of those were new registrant email addresses, who did not attend on Day 1
• ***28 Water Summit Remote Sites**
Web and Social Media Stats

• PSA site Google analytics
  • From January 22 launch of the Water Summit page until March 4, the water summit landing page logged 2,044 (1,647 as unique) pageviews.

• Day 1 Tweet Impressions: Day 2 Tweet Impressions:
Objectives

• Discuss the diverse ways water is being used on farms across the country, and challenges/concerns related to current standards for water quality and testing.

• Discuss and develop minimum standards, practices, or approaches to identified challenges and concerns based on existing PSR requirements that control hazards.

• Recommend actionable next steps related to the standards, practices or approaches that address the identified challenges and concerns.
Objectives

• Discuss the diverse ways water is being used on farms across the country, and challenges/concerns related to current standards for water quality and testing.

• Discuss and develop minimum standards, practices, or approaches to identified challenges and concerns based on existing PSR requirements that control hazards.

• Recommend actionable next steps related to the standards, practices or approaches that address the identified challenges and concerns.
Report Out at End of Day 2

• Concern about the quantitative standard
• Issues include:
  • Acknowledged the standard is science based, but concerns that the science is not specific agricultural water uses
  • MWQP is based on past (years old) data
  • Concerns about allowance of die-off
    • Lack of confidence that it “provide an adequate level of public protection”
• Solutions:
  • Build a new standard
  • Utilize alternatives; Concerns about alternatives
    • Too much pressure on growers to know good science when they see it
    • If everyone uses an alternative, why is there a standard
  • Fix it in Guidance; How much can be fixed in Guidance
Big Group Report Out

• Took poll regarding current rule (water)
  • 30 voted to get rid of the rule in its current state
  • 14 voted to keep it
  • The rest of abstained; Does not include remote people

• **Reasons the rule should stay the same: (14 votes)**
  • The Rule should not be changed without having a known, better option (fear of the unknown)
  • Industry is already meeting the standard
  • Grower confusion surrounding any new requirements/standards (“moving the goal post for growers to meet”)
  • Growers like having a numerical standard to meet
  • Regional concern about water quality
  • Regional concern about enforcement of the standards
    • Enforcing what is in the Rule versus interim guidance
Reasons the Rule Needs to Change

• Concerns about relevance of science that supports it
  • Quantitative standard
  • Die-off allowance
  • Many questions about public health protection and criteria
• Method of calculating the MWQP, namely over four years, where the previous years impact the number.
• Does not incorporate historical water testing data
• FDA is not required to re-evaluate the rule based on new science
• Shift standard to incorporate qualitative aspects such as risk assessment/sanitary survey. The current quantitative criteria are too strict/rigid
• Are current testing methods adequate regarding confidence intervals in the rule criteria?
• Are the current standards protective of the farmer?
  • If a grower is implicated in an outbreak and they have followed the rule as is or used the die-off provision, will they be protected?
Participants Who Abstained

• Would like to keep a numerical standard, not the MWQP
  • Do not agree with the sampling/testing requirements to meet the standards; includes frequency of testing
• Should be able to use historical data
  • Do not exclude based on the timing of testing, as it is currently stated in the Rule
• Keep in mind that buyers will take any Rule requirements and incorporate them into the buyer standards. These buyer standards will continue to become more stringent.
  • Buyers will incorporate FDA guidance into their standards, regardless of if it is in the Rule - This was ‘starred’ as a significant point of discussion.
• What are the consequences of non-compliance for growers? More information is needed.
• Significant concern about water source and 6 hour hold time requirements
• The Rule currently contains no specific triggers – what do the qualitative requirements mean to a grower (if there are no buyer standards)
Fodder for the Panel

• Regardless of how people voted, there were some universal concerns that highlight real issues with the rule
• Everyone recognizes the need for food safety, but growers want to implement practices that are relevant
• Lots of comments about the need for specific assistance/guidance/educational materials/common word usage
• Panel thoughts on how to address these issues....
Got Questions?

Remember to submit your questions to the Q&A team!

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Produce Safety – State Regulatory vs. Non-Regulatory Programs

• Joe Reardon, North Carolina
• Leanna Skelton, USDA
Produce Safety
State Regulatory vs Non-Regulatory Programs

Joe Reardon
North Carolina Dept. of Agriculture & Consumer Services and NASDA

Leanne Skelton
USDA AMS Specialty Crops Program and Liaison to FDA on FSMA-related issues
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Office of Partnerships: Updates and Introduction of Staff

- Barbara Cassens, FDA
- Alicia Schroder, FDA
- Office of Partnerships Staff
FDA Office of Partnerships
2018 Produce Consortium Update

Barbara Cassens
Alicia Schroder
FDA Office of Partnerships Produce Group Personnel Update
Office of Partnerships Produce Group

- **Alicia Schroder**, Office of Partnerships Produce Group Supervisor
  - Alicia.Schroder@fda.hhs.gov / Ph: 425-582-3148

- **Lara Snyder**, Project Officer
  - NASDA CAP Project Officer
  - Lara.Snyder@fda.hhs.gov / Ph: 443-240-4457

- **Denise Beuttenmuller**, Project Officer
  - State CAP - AL, AR, FL, GA, LA, NC, OK, SC, TN, TX, VA, KS, MO, IN
  - Denise.Beuttenmuller@fda.hhs.gov / Ph: 240-506-7618

- **Graham Giesen**, Project Officer
  - State CAP - AK, AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, NE, IA, MN
  - Graham.Giesen@fda.hhs.gov / Ph: 214-790-4986

- **Doreen Gubbay**, Project Officer
  - State CAP - CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT, WV, WI, MI, OH
  - Doreen.Gubbay@fda.hhs.gov / Ph: 240-778-9220
CAP Administration and Monitoring Update
Year 2 CAP Overview

• 43 State Grantees (40 Competition A/B, 3 Competition A Only)
• Year 2 Budget Period: July 1, 2017 to June 30, 2018
• Total new FDA Investment in State CAP in Year 2: $30.2 Million
• The focus of Year 2 is dedicated to:
  • Continuation of Unaccomplished Year 1 work
  • Education and Outreach Activities
  • Establishing an Inspection and Compliance Program
2017 – 2018 Grantee Map

Competition A Only & Competition A / B Map

Competition A includes Infrastructure, Education, Technical Assistance, and Inventory Program.

Competition A/B includes Competition A components AND an Inspection, Compliance and Enforcement Program.
CAP Program Administration
Monitoring Activities

- Monitoring may be in the form of, but not limited to, telephone conversations, e-mails, visits, or written correspondence between the project program office/grants management office and the principal investigator.

- Frequency of monitoring may vary according to the specific program objective, grantee or issue.
CAP Program Administration Reporting

Mid-Year Progress Report
- A Mid-Year Progress Report is to be submitted 30 days following the end of the first 4 months of the budget period
  - DUE December 1 each year

Annual Progress Report
- Due as part of the Research Performance Progress Report (RPPR) submitted through eRA Commons 60 days before the end of the budget year
  - DUE May 1 each year
CAP Program Administration
Performance Measures

• Eight Performance Measures were identified in Year 1 and those measures will remain in place through Year 2
  • Tracked in the Performance Measure Workbook

• Additional Performance Measures are being developed for Year 3 and will be shared by FDA as soon as they are available
CAP Collaboration and Information Sharing Update
FDA Hosted Webinar Series

• Webinars are scheduled for the fourth Wednesday of most months. These webinars are organized and hosted by OP Produce Group; however, the topics and presentations are a collaborative effort by all involved with PSR implementation.

• Webinars provide current thinking and guidance on Produce CAP specific topics and is platform for grantees to share successes.

• Webinar attendance is considered mandatory for grantees.

• Webinars are recorded and posted with associated documents and are available on FoodSHIELD.
FoodSHIELD

FoodSHIELD workgroup name:

FDA Produce Safety Cooperative Agreement Programs

- Collaboration space for all CAP stakeholders (includes FDA, NASDA, Grantees, Subawardees, etc.)
- Access to FDA Webinar presentations, documents and recordings
- Location of NASDA sub-workgroups folders
- Location of Guidance and Reference Documents
- Shared Member List
- Reference Link Library
- Anyone working on the CAP is welcome to have access to this site; please contact your project officer to obtain access
Information Sharing Agreements

• Efforts underway to get partners (who are able) into 20.88 Information Sharing Agreements

• We are anticipating a Produce Specific 20.88 intended for State Education Extensions to be forthcoming in the next month or so
  • That information is available it will be distributed to grantees via the OP Produce Group
CAP Financial Update
CAP Financial Spending

• Spend funding as planned in budgets submitted

• Reallocate funding as appropriate to meet evolving Program goals and objectives
  • Prior Approval for cumulative or single changes greater than 10%

• Draw down funding from FDA regularly/timely
  • Drawing down funds will help both the FDA and your agency assess your budget requirements and assess your funding needs
CAP Financial
Year 3 and Carryover

• FDA is committed to fully funding grantees to get the funding needed to develop and implement their programs

• FDA is in the process of making final decisions on carryover guidance for Year 2
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Produce Safety Alliance Update

- Betsy Bihn, Produce Safety Alliance
Produce Safety Alliance Update

• Significant progress on training growers and developing trainers
• Supporting growers and trainers as questions arise and new materials are needed
• International collaboration represents some unique challenges
• Funding for PSA moving forward is needed
<table>
<thead>
<tr>
<th>Grower Training Courses</th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Total GT Courses since</td>
<td>Domestic</td>
<td>385</td>
</tr>
<tr>
<td>Sept 2016</td>
<td>International</td>
<td>206</td>
</tr>
<tr>
<td>Total</td>
<td>Total</td>
<td>591</td>
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<tr>
<td>Total Grower Participants</td>
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<td>14,104</td>
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<tr>
<td>Average GT Course Size</td>
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<tr>
<td># States Hosting GT</td>
<td></td>
<td>47</td>
</tr>
<tr>
<td>Courses</td>
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</tbody>
</table>
Kansas in Feb 2018
North Dakota in March 2018 with Tribal Nations & April 2018
Still working on Wyoming
<table>
<thead>
<tr>
<th></th>
<th>Domestic</th>
<th>International</th>
<th>Total</th>
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<tbody>
<tr>
<td>Total TTT Courses</td>
<td></td>
<td></td>
<td>49</td>
</tr>
<tr>
<td>since Sept 2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Trainer Participants</td>
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<td></td>
<td>1,567</td>
</tr>
<tr>
<td>Average TTT Course Size</td>
<td></td>
<td></td>
<td>31</td>
</tr>
<tr>
<td># States Hosting TTT Courses</td>
<td></td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>
PSA Team coordinates the review of Lead Trainer and Trainer of Trainer Applications
<table>
<thead>
<tr>
<th>PSA Lead Trainers by Region</th>
<th>PSA Trainers by Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>30</td>
</tr>
<tr>
<td>North Central</td>
<td>35</td>
</tr>
<tr>
<td>South</td>
<td>55</td>
</tr>
<tr>
<td>West</td>
<td>60</td>
</tr>
<tr>
<td>Northeast</td>
<td>188</td>
</tr>
<tr>
<td>North Central</td>
<td>219</td>
</tr>
<tr>
<td>South</td>
<td>419</td>
</tr>
<tr>
<td>West</td>
<td>425</td>
</tr>
</tbody>
</table>

| Total PSA Trainers          | 1,480                 |
|                            | 1,251 (D), 229 (I)    |
| Total PSA Lead Trainers     | 197                   |
|                            | 180 (D), 17 (I)       |

| Number of states with PSA Trainers | 49 |
| Number of states with PSA Lead Trainers | 45 |
Unique Outreach & Assistance

• Capacity building nationwide and within State Departments of Agriculture & Health (e.g., new hires, building produce safety teams)
• Mentoring and co-training PSA Trainers & Lead Trainers
• Connect states to existing resources and help identify and address critical resources to address diversity of growers and farming practices in their region/state
• Focus on helping growers maintain farm viability and market expansion, in addition to PSR compliance
  • e.g., farm food safety plan writing workshops, dialog with produce buyers
PSA Helps Facilitate Dialog

• **Soil Summits**
  – Houston, TX – December 12-13, 2017
  – Atlanta, GA – January 21-22, 2018

• **Water Summit**
  – Covington, KY – February 27-28, 2018
  – Remote options were available

• **Other dialog efforts**
  – Grower focus groups
  – Working Committees
  – Educator’s Group
  – National Listserv
PSA Resources & Materials

• PSA Grower Training & Train-the-Trainer Curriculum (Spanish & English)
• Supplemental fact sheets and teaching add-ons
  • Updates on agricultural water (PPT)
  • Cleaning & Sanitation Activity (Photos)
  • Post-harvest Sanitizer Tool (Excel)
• Required PSR records (Word template)
• Exemptions & Exclusions (PPT)
• And much more!
Next Things to Come

• PSA Grower Training in every state

• Online PSA Grower Training Course
  ▪ Initial pilot with growers, collaborators, and regulators is complete
  ▪ Final modules being constructed

• More educational materials

• On-Farm Readiness Review participation
PSA Curriculum Meets Growers’ Needs

- All grower categories reported at 91% or more that there were no learning objectives and critical concepts that were unclear.
- All grower categories reported at 92% or more that the level of FSMA PSR information provided in the curriculum materials was sufficient to guide them in implementing regulatory requirements.
Areas of Concern

• In all grower categories, some still not sure if they are covered or not by the rule
• Rule is seen as a moving target
  • Soil Amendments still reserved
  • Water has proposed extension
• Concern about developing international PSA Trainers and Lead Trainers
• Concerns about translations
• Concerns about PSA funding
Why is PSA funding important for FSMA PSR implementation?

• Current PSA funding ends September 2019, before:
  • Implementation dates for smallest farm category
  • Biological soil amendment and probably Ag Water subparts are settled
• Small growers will need training and resources to regulatory demands and market demands, regardless of exemptions
• Growers need consistent messaging on PSR updates
• PSA Team has unique understanding and dedication to PSR education and outreach
• Network of PSA Trainers & Lead Trainers will need updated information to ensure consistent, quality trainings
• PSA curriculum will need updated as the PSR evolves
Initial results from LFSC Survey

Never Attended PSA Training (%) vs. Compliance Date & Sales

<table>
<thead>
<tr>
<th>Compliance Date / Sales</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>$500k+</td>
<td>51%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>$250k-499,999</td>
<td>64%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$25k-249,999</td>
<td></td>
<td></td>
<td>78%</td>
<td></td>
</tr>
<tr>
<td>$0-24,999</td>
<td></td>
<td></td>
<td></td>
<td>92%</td>
</tr>
</tbody>
</table>
Summary

- PSA is collaborating broadly to achieve its goals
  - Significant interactions with states and others
- Providing unique resources
  - Expertise within the team
  - Additional educational materials
  - Hosting Summits (Soil and Water)
- Funding is a huge concern
  - Small team but critical mass to be effective
The PSA Website
http://producesafetyalliance.cornell.edu/

- Like us on Facebook!
- Or Follow us on Twitter!

@Produce_Safety

Join the listserv

Elizabeth A. Bihn, Ph.D., Director, eab38@cornell.edu, 315.787.2625
Gretchen L Wall, M.S., Coordinator, glw53@cornell.edu, 607.255.6806

The Produce Safety Alliance (PSA) is a collaboration between Cornell University, FDA, and USDA to prepare fresh produce growers to meet the regulatory requirements included in the United States Food and Drug Administration’s Food Safety Modernization Act (FSMA) Produce Safety Rule.

Welcome to the Produce Safety Alliance Website

Stay up-to-date!

Read our latest newsletter: January 2017
August 2016 PSA Factsheet

Join the PSA Listserv!

The listserv is a great way to receive the most current information related to educational and training opportunities, FSMA updates, and produce safety research and events.
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Dispute Resolution Update

• Bob Ehart, NASDA
• Michael Rogers, FDA
2018 Annual Meeting

National Consortium for Produce Safety Program Development

March 6 – 8
Irvine, California

NASDA
FDA – Enforcement Discretion Policy and Other Updates; Update on Guidance

• Samir Assar, FDA
FDA FSMA Update on Guidance/Enforcement Discretion

Dr. Samir Assar
Director of the Division of Produce Safety
CFSAN/FDA

National Consortium for Produce Safety
March 2018
Enforcement Discretion Policy for Certain FSMA Regulations

• Announced January 2018 that FDA intends to exercise enforcement discretion for certain provisions in four of the FSMA Rules

• Applies to certain provisions in the PC Human Food, PC Animal Food, FSVP and Produce Safety Rules

• Allows time for FDA to consider changes or other approaches to address concerns
Enforcement Discretion Provision Areas

• Facilities conducting farm-related activities
• Written Assurances in the PCHF, PFAF, FSVP and Produce Safety Rules
• Importation of Food Contact Substances under FSVP
• Manufacturing/Processing activities for human food by-products for use as animal food
Agricultural Water Requirements

• Based on feedback from stakeholders, FDA is exploring ways to simplify the agricultural water requirements
• Proposed rule to extend the compliance dates for agricultural water for covered produce (other than sprouts), published November 2017
  – January 26, 2022 for All Other Businesses
  – January 26, 2023 for Small Farms
  – January 26, 2024 for Very Small Farms
• Final Rule is under development
FDA Industry Guidance

• Does not establish legally enforceable responsibilities

• Describes the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited

• Industry may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations

• Typically issued in draft with open comment period
Published FSMA Guidances for Produce Industry

- Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement
  - Published Draft in January 2018
  - Comment Period closes May 25, 2018
  - Primarily impacts FSVP and Produce Rule
  - Applies to §§ 112.12 and 112.49 (Alternatives) and 112.171-182 (Subpart P – Variances)) of the Produce Safety Rule
Published FSMA Guidances for Produce Industry

• Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations
  – Draft published in January 2017
  – Intended to assist sprout operations in complying with the sprout-specific requirements and briefly discusses certain other Rule requirements from the perspective of a sprout operation (e.g., certain requirements in Subparts E and L).
  – Received 46 comments; Final guidance under development
Published FSMA Guidances for Produce Industry

• Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation - Small Entity Compliance Guide
  – Published in September 2017
  – Intended to assist small entities in complying with the Produce Safety Rule
Published FSMA Guidances for Produce Industry

• Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA

• Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities
Upcoming Draft Guidance Issuance

• Draft Compliance & Implementation (C&I) Guidance for the Produce Safety Rule
  – Engaged with representatives from NASDA and States during drafting process
  – Addressing feedback received
  – Planning public meetings to engage with stakeholders on draft guidance
  – Communications pieces to accompany draft
Questions?
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State Perspective on Guidance

• Martha Roberts, Florida
States’ Perspective on Guidance
Martha Roberts

• Anxiety in anticipation of guidance issuance
• Full commitment to a preventive system
• Difficulty in measuring whether or not a measure provides the same level of public health protection
• Difficulty in proving comparable measures/metrics
GUIDANCE – FDA & NASDA

• Appreciation for opportunity to provide input in guidance development
• Need for recognition of straightforward language and use friendly basic materials
• Words matter – regulators – farmers don’t speak the same language
• Less is more – Lengthy guidance not effective and less utilized
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

- **Does your farm grow, harvest, pack or hold produce?**
  - **NO**
  - Your farm is NOT covered by this rule.
  - **YES**
    - **Does your farm on average in the previous three years have $25k or less in annual produce sales?**
      - **YES**
      - Your farm is NOT covered by this rule.
      - **NO**
    - **Is your produce one of the commodities that FDA has identified as rarely consumed raw?**
      - **YES**
      - This product is NOT covered by this rule.
      - **NO**
    - **Is your produce for personal/on-farm consumption?**
      - **YES**
      - This produce is NOT covered by this rule.
      - **NO**
    - **Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?**
      - **YES**
      - This produce is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(4).
FDA’S RESPONSIVENESS

• Working with NASDA and States on Implementation/ GAO 3-5 Report
• Working to consensus through workgroups
• Responding to CPS Consortium with additional approved EPA methods
• Leadership through PSA Water Summit
• Fundamental funding of Produce Safety State Implementation Cooperative Agreements
NASDA Model Framework
for Produce Safety Implementation
FRAMEWORK PROVIDES FOUNDATION
States Choose the Design Right for You

2 ROOM CABIN IN THE WOODS

HGTV 2016 DREAM HOME
DR. ASSAR’S ANALOGY THAT GUIDANCE IS ADDING THE FURNITURE – THE DETAILS
All industry wants is a simple chair, limited parts, clear understanding
CONCERNS

• Insecurity with the unknown – need for transparency/ availability of TAN answers

• Flexibility for alternative approaches appreciated but concerns on how to substantiate the alternative scientifically

• Alternatives do not require pre approval but what happens when inspector questions?

• Speed in responding to outbreaks so preventive measures can occur and problems corrected quickly
CONCERNS CONT’D

• FDA isn’t responsible YET with Buyer demands/guidance becomes de facto regulation even though legally non binding
• Critical need for user friendly plain language materials/decision trees
• Guidance will be too complicated
• Continued industry/regulatory concern that regulation and guidance will be focused solely on domestic production
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Planning for Year 3: Cooperative Agreement

Deliverables, Goals, and Objectives

• Shelley Phillips, California
• Abbey Willard, Vermont
• Anita Macmullan, North Carolina
Meet the Team
Program Activities

➢ Farm Inventory
➢ Recruitment
➢ Education
➢ Outreach
➢ OFRR
➢ Enforcement
Farm Inventory

- Status
- Sources
- Unique identifier
  - CA-county number-random number
    (e.g., 05-10-552157)
Recruitment

- Regions
- Current staff
- New hires: July 2018
- Training & Development
## Staff Training

<table>
<thead>
<tr>
<th>Produce Safety</th>
<th>Recommended</th>
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<tbody>
<tr>
<td>PSA Grower Training</td>
<td>CPR &amp; 1&lt;sup&gt;st&lt;/sup&gt; Aid</td>
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<tr>
<td>FDA PSR Regulators Course</td>
<td>Business Writing</td>
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<tr>
<td>FDA PSR online</td>
<td>Conflict Resolution</td>
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<tr>
<td>FDA Horticulture online</td>
<td>Working w/Difficult People</td>
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<tr>
<td>ISO 9001</td>
<td>Analytical/Critical Thinking</td>
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<tr>
<td>USDA Harmonized</td>
<td>Emotional Intelligence</td>
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<tr>
<td>LGMA</td>
<td>Aseptic Training</td>
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<tr>
<td>Preventive Controls</td>
<td>Public Speaking</td>
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<tr>
<td>OFRR training</td>
<td>Discovering &amp; Working w/Your Talents and Strengths</td>
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<tr>
<td>HACCP</td>
<td>Strengths Finder</td>
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<tr>
<td>USDA Fundamentals of Auditing</td>
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</table>
Farmer Education

- Grower training (current year)
- Additional contracts (year 3)
- ID course needs (year 4)
Outreach

- Website
- Press Releases
- Social Media
- Fairs, farm shows, conferences
- Industry meetings
OFRR

- Introduction
- WAQ
- Commodity groups
- Individual farms
Enforcement

- Inspections
- Inspection checklist
  - Prioritizing farms
  - Size, geography, commodities
Closing Point

- Moving in the right direction!
- Reaching farmers
- Education
- Website
- Inspections
For More Information

- Steve Patton, CDFA, Inspection & Compliance Branch, Branch Chief  
  (Steve.Patton@cdfa.ca.gov)

- Shelley Phillips, CDFA, Produce Safety Program, Senior Environmental Scientist – Supervisor  
  (Shelley.Phillips@cdfa.ca.gov)
Vermont Produce Program

Year 3
Development AND Implementation of the Inspection Program

Abbey Willard
Vermont Agency of Agriculture, Food and Markets
Objectives of the Vermont Produce Program

1. FSMA Produce Safety Rule will impact Vermont farmers and we want a local liaison between industry and FDA
2. Ensure that producers can meet market demand for food safety and compete in the regional marketplace
3. Provide education and technical assistance to ensure compliance prior to enforcement (“educate before—and while—you regulate”)
4. Support public health
5. Achieve market access and meet buyer demand
What will the VT Produce Program do in Year 3?

1. Build produce farm inventory
2. Develop regulatory program and hire inspector
3. Collaborate with UVM Extension to deliver education & technical assistance
4. Conduct On-Farm Readiness Reviews (OFRR)
5. Conduct FSMA inspections on covered farms
# Year 3: Vermont Produce Program Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Cooperative Agreement Role</th>
<th>% FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbey Willard</td>
<td>Principal Investigator</td>
<td>variable</td>
</tr>
<tr>
<td>Rachel Floyd</td>
<td>CP Section Chief</td>
<td>?</td>
</tr>
<tr>
<td>Kristina Sweet</td>
<td>Program Manager</td>
<td>90–100%</td>
</tr>
<tr>
<td>Dominique Giroux</td>
<td>Outreach &amp; Education</td>
<td>100%</td>
</tr>
<tr>
<td>Tucker Diego</td>
<td>1st Inspector</td>
<td>100%</td>
</tr>
<tr>
<td>TBD</td>
<td>2nd Inspector</td>
<td>100%</td>
</tr>
<tr>
<td>Trevor Audet</td>
<td>Communications</td>
<td>40%</td>
</tr>
<tr>
<td>Chris Bliven</td>
<td>IT Systems Developer</td>
<td>20%–50%</td>
</tr>
<tr>
<td>Katie Pohl</td>
<td>Attorney</td>
<td>20–40%</td>
</tr>
<tr>
<td>Dan Lynch</td>
<td>Food Systems Coordinator</td>
<td>40%</td>
</tr>
</tbody>
</table>
Infrastructure

• Hiring and training all staff
• Budget tracking and planning
• Inventory portal development
  • Build upon user interface & administrator function, and reporting features
  • Inspection component
• Challenge: unknown FDA IT system
Outreach & Technical Assistance

• Full time Outreach & Education coordinator
  • Messaging to industry about benefits to compliance
  • Outreach resources: ‘Breaking Down the PSR’ series, videos
  • Workshops to facilitate peer to peer sharing
• On Farm Readiness Reviews
  • Calibration within state and NE region
  • OFRR prioritization – need and coverage
• Challenge: Buyer engagement to ensure market access
Inspectional Approach

• What to expect & sharing with peers
• Visiting produce operations
• Decision about whether our agency will continue to offer GAP audits
• Drafting enforcement penalty matrix, templates for NOV and LOW
• Challenge: ground truthing NASS data
Year 3: Development AND Implementation of the Inspection Program

- Adapting to a shifting environment
- Tell the produce industry story
- Continue to break down the Produce Safety Rule for the industry
- Cultivate relationships at the local, regional, and national level
Contact Us

Vermont Agency of Agriculture
Produce Program Team

http://agriculture.vermont.gov/produceprogram

AGR.FSMA@vermont.gov

(802) 522-3132
Planning For Year Three – Deliverables, Goals and Objectives

North Carolina         Tier 3        Competitions A and B

Year 3 Focus: Collaboration Outreach and Education Infrastructure Inspection

OFRR
Collaboration

NC Fresh Produce Safety Task Force

NCD&African CS Research Stations

North Carolina State University
Outreach and Education

Support PSA training conducted by NCSU

Association and Growers Meetings

Research Station Training Centers

On-farm educational visits
On-Farm Readiness Reviews

Training for reviewers in April 2018

Subcontract with NCSU – Dr. Chris Gunter

NCSU FSMA Area Specialized Agents
Inspection

Ensure Statutory and Regulatory Authority

Develop Inspection and Compliance Strategies

Align with NASDA Model Produce Safety Implementation Framework

Training
Infrastructure

IT for Inventory and Inspection program

Facilities

Equipment

Hiring
In Closing...

Year 3 is a key year in program development
Planning is critical to meeting milestones

Anita MacMullan
NCD&A&CS, Food and Drug Protection Division
anita.macmullan@ncagr.gov
919 857 4180
Got Questions?

Remember to submit your questions to the Q&A team!

Two ways to submit questions:

1. By email at FSMAQuestions@nasda.org
2. Written questions are being accepted at the resource table in the back of the room
Produce Safety Network – Updates

• JoAnn Givens, FDA
• Stephen Hughes, FDA
Produce Safety Network
Roles and Responsibilities

• Technical Assistance
• Stakeholder Engagement
• Education and Training
• Outbreak Investigations
• Inspections
• Work-planning
Produce Safety Network
Technical Assistance

• PSR and implementation-related questions
  – >125 questions about the PSR
  – Average response time is ~ 6 days (median – 2 days)
Produce Safety Network
Technical Assistance

• PSR and implementation-related questions
  – Members are working on resource materials to assist stakeholders with understanding the Produce Safety Rule.
Produce Safety Network
Roles and Responsibilities

• Technical Assistance

• Stakeholder Engagement
  • Education and Training
  • Outbreak Investigations
  • Inspections
  • Work-planning
Produce Safety Network
External Stakeholder Engagement

- PSN members have attended >100 events during 2017 to engage directly with those impacted by the Produce Safety Rule.
- More stakeholder engagement planned for 2018, focused on ag water and supporting the roll-out of guidance.
Produce Safety Network
Internal Stakeholder Engagement

• District/Division Engagement.
  • Not co-located within Districts/Divisions.
  • Establishing relationships with District Directors, State Liaisons, Emergency Response Coordinators.
  • Engage in work-planning.
Produce Safety Network
Roles and Responsibilities

• Technical Assistance
• Stakeholder Engagement

• **Education and Training**
• Outbreak Investigations
• Inspections
• Work-planning
Produce Safety Network
Educational Farm Tours

• Educational farm visits domestically and internationally
  – Learn more about the unique growing conditions, practices, and compliance challenges
  – Interact with growers and hear their perspective
  – Share information about the Produce Safety Rule and implementation
Produce Safety Network
Supporting International Training

• A collaboration between FDA, JIFSAN, and PSA to adapt the standardized curriculum to international audiences.
• First train-the-trainer training under the PIP occurred in Jamaica in 8/2017.
• Additional trainings throughout Central and South America.
Produce Safety Network
Training Development

• Produce Safety Regulator Curriculum for FDA and State Regulators:
  – PSA Grower Training
  – Produce Rule web course
  – Horticultural practices web course
  – Produce Inspection Course (in-person)
  – Produce/Sprout Investigation course
  – Produce Safety Inspection for Regulators
Produce Safety Network
Roles and Responsibilities

- Technical Assistance
- Stakeholder Engagement
- Education and Training
- Inspections
- Work-planning
- Outbreak Investigations
Produce Safety Network
Domestic and Foreign Farm Inventory

• Foreign Inventory
  – ORA PSN is currently working to develop a foreign farm inventory.
  – As foreign farms were in the past inspected under the FD&C Act, a basic framework was in place for the workgroup to build upon.

• Domestic Inventory
  – FDA has received a list of domestic farms from Dunn and Bradstreet.
  – We will need to verify the information.
Produce Safety Network
Foreign Inspections/International Outreach

• PSN has conducted 18 foreign inspections (produce farms);
• PSN have also conducted outreach and educational activities when in foreign countries.
Produce Safety Network
Outbreak Response

• Monitored 8 produce-related outbreaks;
• Conducted 2 produce investigations;
• Assisted in sewage spill affecting strawberry field;
• Assisted State in an investigation on a produce farm associated with a STEC O103 outbreak.
Produce Safety Network

Disaster Response

- Sewage spills;
- Hurricanes.
For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
QUESTIONS/DISCUSSION
Summary of 2018 Produce Safety Consortium Meeting/Panel Comments and Q&A

• Bob Ehart, NASDA
• Joe Reardon, North Carolina
• Mel Plasier, FDA
• Erik Mettler, FDA
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Remember to submit your questions to the Q&A team!

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1. By email at FSMAQuestions@nasda.org

2. Written questions are being accepted at the resource table in the back of the room
Going Forward from Here – Vision, Charge, Next Steps

• Bob Ehart, NASDA
• Joe Reardon, North Carolina