Produce Regulatory Program Standards (PRPS)

Building Stronger State Produce Programs

- PRPS Development/Initial Committee
- Implementation Group Transition (IG)
- Information Sharing Leadership Team
  1. Emergency Response Workgroup
  2. Information Collection and Sharing Work group (CFSAN request)

     Lead State Chair
     - Pilot Chair
     - Transition to Ecosystem 7/11
  3. Inspection Frequency Workgroup
- NECAFs Advisory Board/Regulator Chair
- AFDO Produce Committee
- PSA support/UMASS Funding/Fireman

Standards – What Are They?

- A holistic set of elements for a quality regulatory program
- Organized by subject areas
- Provides a road map/business plan, with built in flexibility to address your program's specific needs
- Published by FDA
  - Technical support leads in OP/Division of Standards Implementation
- Existing standards – MFRPS, AFRPS, ERPS, VNRFRPS

What's In It For Me?

- Business Plan/Model
- Defensible regulatory actions and decisions
- Structured way of thinking about the program
- Clear elements to achieve
- Built-in quality management
- Foundation of mutual reliance with other states
- Job aids to help achieve conformance
- Support from FDA, NASDA, and AFDO as you progress

Benefits for Industry

- Provides a foundation for more uniformity
  - More consistent inspectional processes
  - Promotes more uniform application of the Produce Safety Rule
  - Improved quality of inspections to help farmers identify risks
- Increases consumer confidence in safe produce
- Reduces recalls

Benefits for Inspectors

- Establishes a training plan and continuing education, resulting in effective field activities
- Documents procedures to facilitate training, promotion, and succession
- Improves quality of inspections
- Improves relationships with regulated community with more consistency between inspectors

Benefits for Program Managers

- Business plan for easier program and staff management
  - Built in flexibility to meet local/regional needs
- Defines the framework for a legally defensible program
- Documents procedures for training, workplanning, succession
- Outlines education and outreach activities to strengthen industry relationships

Benefits for Ag Commissioners

- Support from the FDA to ensure a quality program
- Documents processes for a legally defensible position
- Promotes alignment among states without dictating how a state must implement processes
- Protects consumers from unintended outbreaks which damage consumer confidence in agricultural products
- Prepares a program for outbreak and other emergency response

PRPS Development to Present

- Kick-off: March 2022
- Workgroups: March 2022 – November 2022
- Final Development Committee Review: March 2023
- Submitted to FDA: May 11, 2023

Who Wrote Them? – The Development Committee

California	Virginia
Colorado	FDA – OP/Division of Standards Implementation
Massachusetts	FDA – ORA PSN
Minnesota	FDA – CFSAN PSN
Nebraska	FDA - OHAFO/Audit Staff
North Carolina	NASDA
Texas	AFDO (non-voting)

Who Wrote Them? – The Workgroups

	State Participants	FDA SME
Standard 1	**Virginia**, Louisiana, Michigan, Oklahoma	CFSAN PSN
Standard 2	**Texas**, Missouri, South Carolina	OTED
Standard 3	**Massachusetts**, **Minnesota**, Alabama, New Jersey	ORA PSN
Standard 4	**Massachusetts**, Minnesota, Virginia	OHAFO AS
Standard 5	**California**, Minnesota, Rhode Island	RRT
Standard 6	**North Carolina**, Arizona, Michigan, Minnesota	OHAFO AS
Standard 7	**Colorado**, New Jersey, Oregon, Vermont	ORA PSN
Standard 8	**Nebraska**, Indiana, South Carolina	OP/DPIA
Standard 9	**Nebraska**, Missouri, Texas	OHAFO AS
Standard 10	**North Carolina**, Minnesota, Michigan	CFSAN ORS

STANDARDS

(Program Areas)

1. Regulatory Foundation
2. Training
3. Inspection Program
4. Auditing
5. Feed/Food-Related Illnesses and Emergency Response
6. Compliance and Enforcement Program
7. Outreach
8. Resources
9. Assessment
10. Laboratory

1. Purpose
2. Requirement Summary
3. Program Elements
4. Outcome
5. Documentation

- Related Appendices

STANDARD CONTENT

(Organization of each Standard)

Standard 1: Regulatory Foundation

- Evaluate the scope of legal authority
- Evaluate the adequacy of regulatory provisions to ensure the protection of fresh produce
- Compares state laws and rules to FDA's regulatory foundation
- Does not require adoption or incorporation of federal law into state law

Standard 2: Training

- Establish and document a training plan and training records
- Coursework, field training, and continuing education

Standard 3: Inspection Program

- Define inventory
- Define risk profiles
- Document procedures for inspecting, reporting, and reviewing
- Procedures for recalls and complaints
- Procedures for sample collection (if conducted)

Standard 4: Inspection Audit Program

- Procedures for field and desk audits
- Procedures to evaluate, track, trend, and correct
- Ensures quality and consistency among program staff

Standard 5: Foodborne Illness, Outbreak, Response

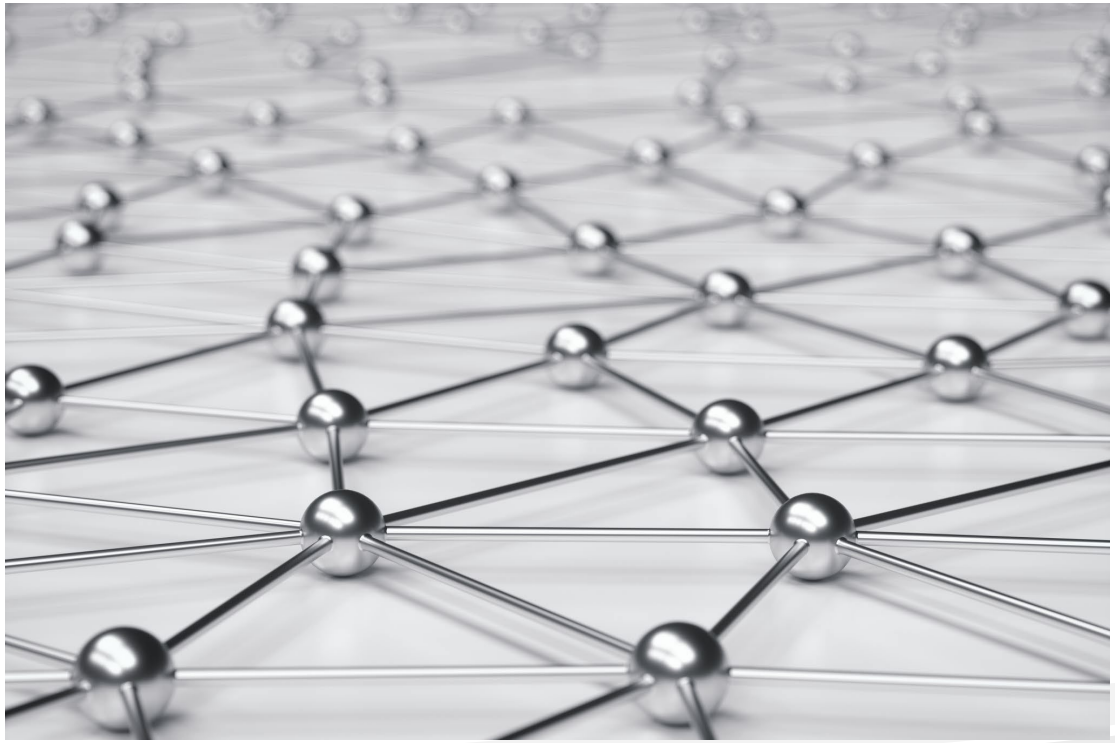
- Procedures to plan for response activities
- Procedures for detection, response, and post-response
- Establishes communication pathways
- Sharing of findings/prevention measures

Standard 6: Compliance and Enforcement Program

- Describe strategies, procedures, and actions to enforce laws and regulations
- Procedures to evaluate effectiveness of the enforcement program

Standard 7: Outreach Activities

- Documents methods for conducting education and outreach
- Evaluation of outreach activities

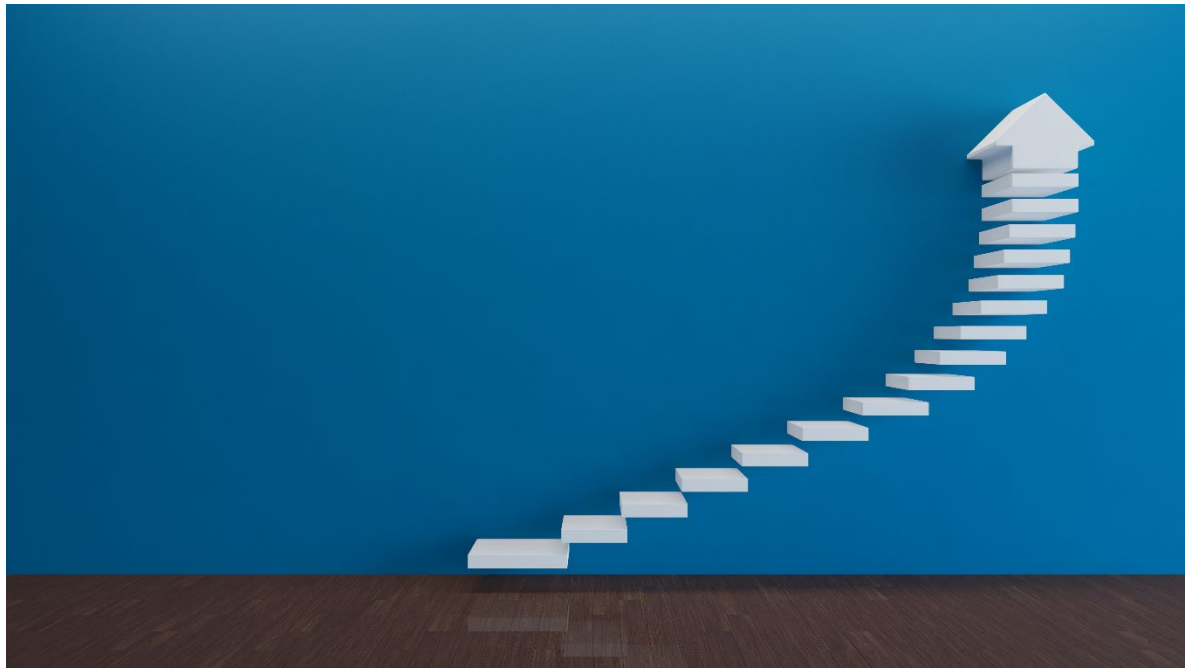


Standard 8: Program Resources

- Procedures for workplanning
- Procedures for resource review to meet the workplan

Standard 9: Program Assessment

- Self-assessments to determine conformance to the PRPS
- Development of a strategic improvement plan
- Document control
- Continuous improvement process



Standard 10: Laboratory Support

- Only if sampling is conducted
- Establishes agreements with the laboratory
- Describes communication between the laboratory and program
- Identifies requirements of the laboratory

What's Next?

- OMB Clearance/Public Comment: Started October 2023
- Update Process Recommendations: to FDA January 2024
- Pilot Program: started January 2024
  - Focused on self-assessments and strategic improvement plan
  - Gather data and feedback
- Additional outreach and education
- Expected formal publication: Fall 2024
- More to come