



# Produce Regulatory Program Standards (PRPS)


Conformance through Communication and Collaboration





## 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, VNRFRRPS



## 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)

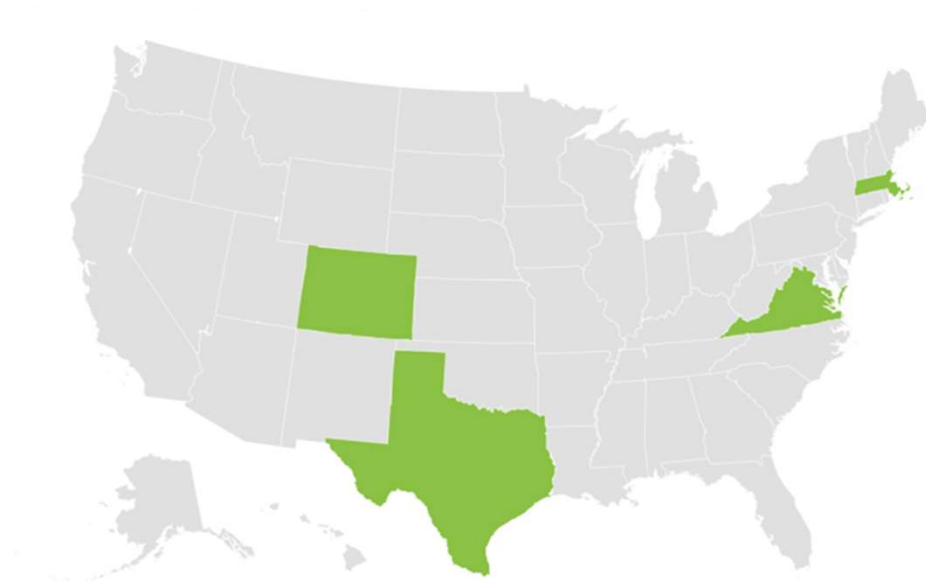
## Who Wrote Them? – The Workgroups

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




## Pilot States

- Texas
- Colorado
- Virginia
- Massachusetts





## What's In It For Texas?

- 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
- 



## 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



## Game Plan

- Assess where we are so we know how to move forward
- Standard 1
- Standard 9



## What are states experiencing

- Standard 1 Authority
  - How to fix gaps
  - Legislation
  - MOU
  - Administrative Rules



## What are states experiencing

- Training
  - Some states are very small
  - Turnover
- Lab support
- Staffing/Time



## What are states experiencing

- Rapid Response
  - some states do not have an RRT
  - some states have RRT in another agency
- Program Assessment
  - Evaluating your program
- FDA support




## Future Concerns

- Keep up with implemented Standards
- Time
- Staffing changes



## What's Next?

- Pilot Program: started January 2024
  - Focused on self-assessments and strategic improvement plan
  - Gather data and feedback
- January 2025 – 6 new pilot states
- Additional outreach and education
- Expected formal publication: Fall 2024



## What's Next?

Creation of the Produce  
Regulatory Program Standards  
Alliance and Board

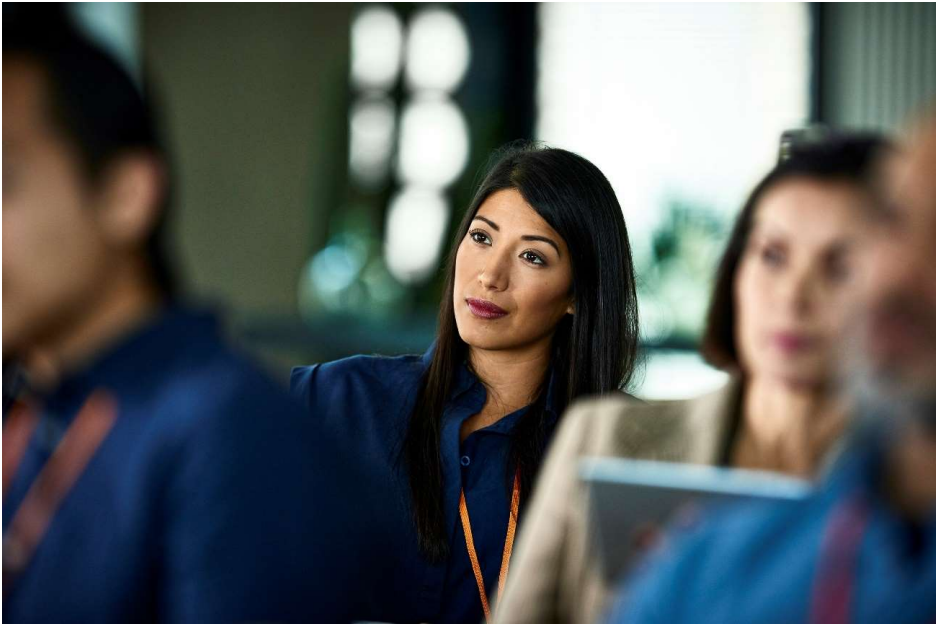


## Standard 1: Regulatory Foundation

- 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



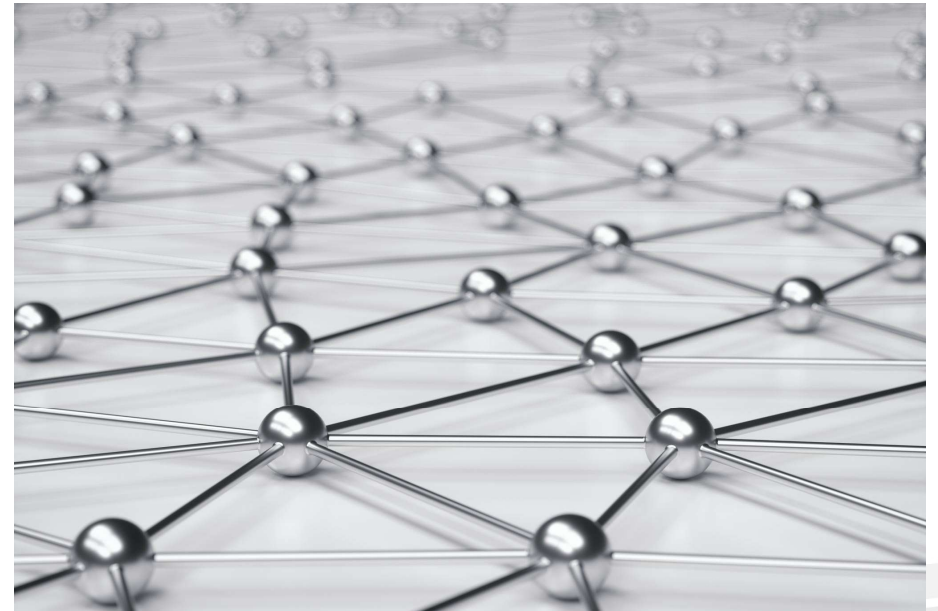
# Standard 6: Compliance and Enforcement Program



- 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



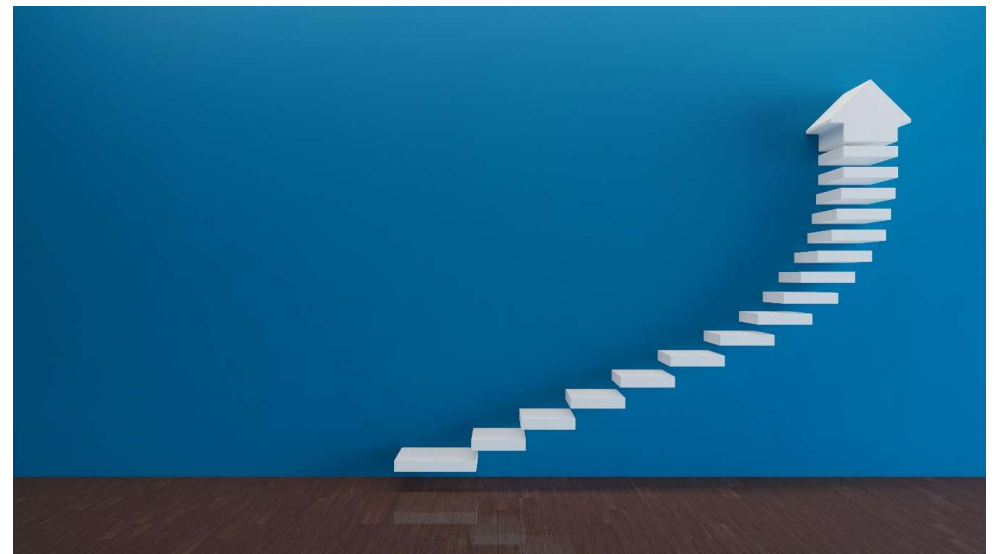
## Standard 8: Program Resources



- Procedures for work-planning
- 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